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APPLICATION NUMBER: ***60/076,698***
FILING DATE: ***March 03, 1998***

PRIORITY DOCUMENT
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET	ATTORNEY DOCKET NO. 10396/46002

Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231
Box Provisional Application

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(b)(2).

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For: **METHOD AND DEVICE FOR DETERMINING BONE CHARACTERISTICS**

1. **21** sheets of drawings, **56** sheets of specification, **13** sheets of claims, and **1** sheet of abstract.

2. Please charge the required application filing fee of **$150**, and any other fees that may be required, to the deposit account of **Kenyon & Kenyon**, deposit account number **11-0600**. A duplicate of this sheet is enclosed.

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Express Mail No. IB 505748562US
182556

60/076,598

[10396/46002]

METHOD AND DEVICE DETERMINING BONE CHARACTERISTICS

FIELD OF THE INVENTION

The present invention relates to an instrumentation for non-destructive measurement of mechanical properties of materials generally and to the instrumentation for non-invasive measurement of the mechanical properties of bone and bone quality.

BACKGROUND OF THE INVENTION

It is known in the art that the velocity of a sound wave in a material depends on the mechanical properties of the material. This phenomena is described, for example, by C.H. Hastings and S. W. Carter in an article entitled "Inspection, Processing and Manufacturing Control of Metal by Ultrasonic Methods," Symposium on Ultrasonic Testing, 52nd Annual Meeting of the American Society for Testing Materials, June 28, 1949, pp. 16 - 47.

U.S. Patents 3,720,098, 3,228,232, 3,288,241, 3,372,163, 3,127,950, 3,512,400, 4,640,132, 4,597,292 and 4,752,917 describe the state of the art of non-destructive testing using ultrasound.

A sound wave which reaches a semi-infinite solid at an angle will typically propagate through and along the solid as three waves, namely, longitudinal, transverse and surface waves, wherein each wave has a different velocity. As described by Hastings and Carter, the velocities of the three waves are:

$$V_L=\sqrt{\frac{E(1-\sigma)}{rho\,(1+\sigma)\,(1-2\sigma)}} \qquad (1)$$

$$V_T=\sqrt{\frac{E}{2(1+\sigma)\,rho}} \qquad (2)$$

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$$V_S = \alpha V_T \tag{3a}$$

$$\alpha = \frac{0.87 + 1.12\sigma}{1 + \sigma} \tag{3b}$$

where V_L, V_T, and V_S are, respectively, the velocities of the longitudinal, transverse and Raleigh surface waves, and E, σ and rho are, respectively, the Young's Modulus, the Poisson's ratio of lateral contraction to longitudinal extension and the mass density of the material. Equation (3b) is an empirical relationship as defined on page 326 of Wave Motion in Elastic Solids, by Karl F. Graff, published by the Clarendon Press, Oxford England in 1975.

In ultrasonic measurement of the condition of bone, typically only the velocity of the longitudinal wave is used. In an article entitled, "Osteoporotic Bone Fragility: Detection by Ultrasound Transmission Velocity," R.P. Heaney et al., JAMA, Vol. 261, No. 20, May 26, 1989, pp. 2986 - 2990, the Young's Modulus of bone, E, is given empirically as:

$$E = K(rho)^2 \tag{4a}$$

The velocity of the longitudinal sound wave in the bone is given as:

$$V_L = \sqrt{(E/rho)} = \sqrt{(K \cdot rho)} \tag{4b}$$

where K is a constant which incorporates a number of factors, such as spatial orientation of the bone structures, inherent properties of the bone material and fatigue damage. Thus, the velocity of a longitudinal wave is a function of the mass density and can be used as an indicator of the quality of bone.

The following articles also discuss ultrasonic measurement of bone condition both *in vivo and in vitro:*

"Measurement of the Velocity of Ultrasound in Human Cortical Bone In Vivo," M.A. Greenfield, et al., Radiology, Vol. 138, March 1981, pp. 701 - 710; and

"Combined 2.25 MHZ ultrasound velocity and bone mineral density measurements in the equine metacarpus and their in vivo applications," R.N. McCartney and L.B. Jeffcott, Medical and Biological Engineering and Computation, Vol. 25, 1987, Nov. 1877, pp. 620 - 626.

In order to perform *in vivo* ultrasonic measurements of the mechanical properties of bone, it is necessary to transmit an ultrasonic wave through the soft tissue surrounding the bone. Unfortunately, the thickness of the soft tissue varies along the length of the bone. This thickness variation can affect the accuracy of the ultrasound propagation time measurement through the bone. In the above-mentioned articles, the thickness of the soft tissue is either ignored or an attempt is made to cancel the effects of the soft tissue. In the articles describing in vitro experiments, the soft tissue is removed from the bone.

Russian patents nos. 1,420,383, 1,308,319, 1,175,435, 1,324,479, 1,159,556 and 1,172,534 and U.S. Patents 4,926,870, 4,361,154, 4,774,959, 4,421,119, 4,941,474, 3,847,141, 4,913,157 and 4,930,511 describe various systems for measuring the strength of bone based on the velocity V_L. These systems typically have one ultrasonic signal transmitter and at least one ultrasonic signal receiver.

Russian patents nos. 1,420,383, 1,308,319 and 1,175,435 attempt to solve the problem of the unknown thickness of the soft tissue by assuming values for the thickness of the soft tissue in the area of the measurement or by assuming that the thickness variation is small over the distance between two ultrasonic signal receivers.

Russian patent no. 1,342,279 utilizes two receivers and a single transmitter and calculates an average group speed through the bone based on the known distance between the two receivers.

Russian patent no. 1,159,556 defines zones of a bone and the condition of a bone is determined by the difference between the maximum and minimum amplitude of the ultrasound signals measured, different zones having different velocities.

It appears that this measurement is performed on an excised bone.

Russian patent no. 1,172,534 describes a system which compares the ultrasound signal of a healthy bone with that of an unhealthy bone and from the comparison, produces a diagnosis of the extent of disease in the unhealthy bone.

U.S. Patent Nos. 4,926,870, 4,421,119 and 3,847,141 describe systems which places a receiver and a transmitter on opposite sides of a bone. U.S. Patent No. 4,926,870 also compares the resultant signal with a canonical waveform, thereby to classify the health of the bone.

U.S. Patent Nos. 4,913,157, 4,774,959 and 4,941,474 describe systems which transmit an ultrasonic signal with a spectrum of frequencies.

U.S. Patent No. 4,930,511 describes a system which is placed around a standard inanimate homogeneous material of known acoustic properties before it is placed around a bone.

U.S. Patent No. 5,143,072, the disclosure of which is incorporated herein by reference, describes a method of overcoming the effects of the unknown thickness of the intervening soft tissue. Fig. 1A, which illustrates the method of this patent, shows an ultrasonic transmitter 2 and two ultrasonic receivers 4 and 6, all of which are collinear. Transmitter 2 transmits an ultrasonic wave through soft tissue 22 towards a bone 18. The first signal received at receiver 4 passes through the fastest path. This path includes a first soft-tissue path portion 8, a bone surface portion 10 and a second soft-tissue path portion 14. An angle 23 between path 8 and path 10 is determined by the ratio between the acoustic velocity in bone 18 and the acoustic velocity in soft-tissue 22. The first signal received by receiver 6 passes through first soft-tissue path portion 8, bone surface portion 10, an additional bone path portion 12 and a third soft-tissue path portion 16. The propagation times for the first received signals at receivers 4 and 6 are measured. If receivers 4 and 6 are aligned so that path 14 and path 16 are of the same length, subtracting the two signal propagation times yields

the signal propagation time in bone portion 12. Since bone portion 12 has the same length as the distance between receiver 4 and receiver 6, the acoustic velocity in bone portion 12 can be determined.

Fig. 1B shows a method disclosed by the '072 patent for assuring that path 16 and path 14 have the same length. Receivers 4 and 6 are also transmitters, and they are used to measure the wave propagation times along paths 30 (and 32) between receivers 4 (and 6) and bone 18. In an additional embodiment disclosed, transmitter 2 and receivers 4 and 6 are mounted on a rocker, which compresses soft tissue 22 when it rocks, such that when the propagation times along paths 30 and 32 are found to be equal, acoustic bone velocity is determined.

However, even this method has several serious shortcomings. First, soft tissue velocity is not a constant, rather, it varies with the type of soft tissue. Since the propagation paths 30 and 32 are not the same as paths 14 and 16, the propagation times along paths 14 and 16 may be unequal and the calculated acoustic bone velocity is not correct, even if the propagation times along paths 30 and 32 are equal. Second, the above described method requires a relatively long portion of flat bone. Thus, only a small number of bones can be tested, using this method, such as the tibia. In addition, since high frequency ultrasonic waves are very glossy, it is not practical to use them for this method. Third, the spatial resolution of this method is relatively low, approximately 2-5 cm.

SUMMARY OF THE INVENTION

It is one of the objects of the present invention to provide a method of acoustic bone velocity determination which has a high resolution. In addition, a small portion of bone can be measured, so that almost all the bones of the human body can be measured using a preferred embodiment of the present invention.

In a preferred embodiment of the present invention, a device and method is provided in which at least one transmitter and at least one receiver are situated on a skin of a patient. A first ultrasonic wave is transmitted along a first transmission path. The first transmission path extends through the interposing medium and along a surface of the solid material. The first travel time of the first ultrasonic wave along the first transmission path is thus measured. A second ultrasonic wave is transmitted along a second transmission path. The second transmission path also extends through the interposing medium and along the surface of the solid material. A second travel time of the second ultrasonic wave along the second transmission path is also measured. Then, a third ultrasonic wave is transmitted along a third transmission path. The third transmission path extends similarly to that of the first and second transmission paths. Thus, a third travel time of the third ultrasonic wave along the third transmission path is measured. Thereafter, a control device determines either the acoustic velocity via the surface of the solid material, an angle of the transmitter and the receiver with respect to the solid material or the distance from the solid material to the skin as a function of the distances between the at least one transmitter and the at least one receiver, and the first, second and third times.

In one embodiment according to the present invention, the transmitters and the receivers are positioned along an axis which extends at an angle from the extension of the bone. Using the method and device as described above, it is possible (contrary to the teaching of the conventional methods and devices) to determine the acoustic velocity even when the transmitters and/or the receivers are aligned at an angle to the extension of the bone.

In yet another embodiment of the present invention, the acoustic velocity of the interposing medium can be calculated (instead of using a predetermined value). In particular, another one of the first transmitter or the second transmitter transmits a fourth ultrasonic wave along a fourth

transmission path. The fourth transmission path extends similarly to that of the third transmission path to reach another one of the first receiver or the second receiver. Thus, a fourth travel time of the fourth ultrasonic wave along the fourth transmission path is measured. Thereafter, a control device determines the acoustic velocity on the surface of the bone as a function of the distances between the transmitters and the receivers, the first, second, third and fourth times and the calculated acoustic velocity in the interposing medium.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A shows a prior art method of acoustic bone velocity measurement.

Fig. 1B shows a prior art enhancement to the method shown in Fig. 1A which includes additional measurements.

Fig. 2 shows a method of acoustic bone velocity measurement according to a preferred embodiment of the present invention.

Fig. 3 shows a method of soft tissue acoustic velocity determination according to a second preferred embodiment of the present invention.

Fig. 4A shows a preferred method of acoustic bone velocity measurement combining aspects of the methods of Figs. 2 and 3.

Fig. 4B shows another preferred embodiment of the invention combining aspects of the methods of Figs. 2 and 3.

Fig. 4C shows the method of Fig. 4A as applied is cases of equal and unequal thicknesses of underlying tissue.

Fig. 4D is a simplified partial schematic of a portion of the method of Fig. 3.

Fig. 4E is a simplified partial schematic of a portion of the method of Fig. 2.

Figs. 5A and 5B show a two step method of acoustic bone velocity measurement according to another preferred embodiment of the present invention.

Figs. 6A and 6B show a two step method of acoustic bone

velocity measurement according to yet another preferred embodiment of the present invention.

Fig. 7A shows yet another embodiment of the method for acoustic bone velocity determination according to the present invention.

Fig. 7B shows a further embodiment of the method illustrated in Fig. 7A.

Fig. 8A shows a first alternative embodiment of the methods illustrated in Figs. 7A and 7B.

Fig. 8B shows a second alternative embodiment of the methods illustrated in Figs. 7A and 7B.

Fig. 8C shows an embodiment of the method and device for acoustic bone velocity determination according to the present invention using a transmitter and a receiver.

Fig. 8D shows another embodiment of the method for acoustic bone velocity determination according to the present invention using two transmitters and two receivers.

Fig. 8E shows yet another embodiment of the device and method for acoustic bone velocity determination according to the present invention using a linear phasable multi-element grid.

Fig. 8F shows a further embodiment of the device and method for acoustic bone velocity determination in which the transmitters and receivers are inclined at a first predetermined pitch.

Fig. 8G shows a further embodiment of the device and method for acoustic bone velocity determination in which the transmitters and receivers are inclined at a second predetermined pitch.

Fig. 8H shows a preferred embodiment of the device and method for acoustic bone velocity determination.

Fig. 8I shows an enlarged view of an exemplary transmitter and/or receiver of the device according to the present invention.

Fig. 8J shows a further embodiment of the method for acoustic bone velocity determination in which the transmitters are arranged in a first configuration.

Fig. 8K shows a further embodiment of the method for acoustic bone velocity determination in which the transmitters are arranged in a second configuration.

Fig. 9 is a partial schematic view of a cut human bone.

Fig. 10 is a graph showing the relationship between the thickness of an object and the velocity of an ultrasonic wave along its surface.

Fig. 11 is a schematic illustration of an alternative embodiment of the present invention utilizing an array of piezoelectric transducers.

Fig. 12 is a schematic illustration of the array of Fig. 11, illustrating the connections of the transducers to control and signal processing elements.

Figs. 13A and 13B show a method of soft tissue analysis according to a preferred embodiment of the present invention.

Fig. 14 shows a method of simultaneous bone-velocity determination and bone imaging according to a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A method of acoustic bone velocity determination according to a preferred embodiment of the present invention includes soft tissue velocity determination. Fig. 2 shows a bone 18 surrounded by soft tissue 22. To measure acoustic bone velocity, a transmitter 40 transmits a signal to a receiver 44, and a travel time T_{total} is measured. Obviously, there are many paths that the signal can take from transmitter 40 to receiver 44, some of which reflect off bone 18 and some which pass along the surface of bone 18.

If a distance D_{4044} between transmitter 40 and receiver 44 is long enough, the fastest path, as shown in Fig. 2, comprises three segments. A first soft tissue path segment 60, a surface bone path segment 64 and a second soft tissue path segment 62. The angle B_r between segment 60 and a perpendicular to segment 64 (bone 18) is the Brewster angle, defined as:

$$B_r = arcsin(V_{22}/V_{18}) \quad (5)$$

where V_{22} is the velocity of a longitudinal wave in soft tissue 22 and V_{18} is the velocity of a longitudinal surface wave in bone 18. If D_{4044} is so short that a Brewster angle cannot be formed, then the fastest path is one of simple reflection off bone 18.

The acoustic velocity in bone 18 is calculated by dividing a length D_{64} of bone segment 64 by the a time T_{64} it took the signal to propagate across bone segment 64. However, neither D_{64} nor T_{64} are known. Some prior art methods estimate V_{22}, a distance H_{40} between transmitter 40 and bone 18 and a distance H_{44} between receiver 44 and bone 18. Thus, a distance D_{60}, which is the length of segment 60, a distance D_{62} which is the length of segment 62 and their propagation times T_{60} and T_{62} are:

$$D_{60} = \frac{H_{40}}{cos(B_r)} \quad (6)$$

$$D_{62} = H_{44}/cos(B_r) \quad (7)$$

$$T_{60} = D_{60}/V_{22} \quad (8)$$

$$T_{62} = D_{62}/V_{22} \quad (9)$$

D_{64} and T_{64} are:

$$D_{64} = D_{4044} - (H_{40}tg(B_r) + H_{44}tg(B_r)) \quad (10)$$

$$T_{64} = T_{total} - (T_{60} + T_{62}) \quad (11)$$

So that V_{18} is:

$$V_{18} = D_{64}/T_{64} \quad (12)$$

Solving the simultaneous equations (5)-(12) yields V_{18}.

However, estimation of H_{40}, H_{44} and V_{22} is not very precise, especially since V_{22} changes as a function of distance from bone 18. Typically, the tissues near bone 18 are muscle and have an average velocity 10% higher than fat, which is typically deposited closer to the skin.

Fig. 3 shows a method of determining H_{40}, H_{44} and V_{22} in accordance with a preferred embodiment of the invention. A transmitter/receiver 42 is collinearly placed between transmitter 40 and receiver 44 such that the fastest path between transmitter 40 and transmitter/receiver 42 has no path segment in bone 18. The fastest path between transmitter 40 and transmitter/receiver 42, as shown in Fig. 3, comprises a first soft tissue segment 46 and a second soft tissue segment 48. A method of placing transmitter/receiver 42 in such a location is to:

(a) estimate the Brewster angle; and

(b) place transmitter/receiver 42 at a location wherein a reflection angle R_r which is the angle between segment 46 and a perpendicular to bone 18, is smaller than the Brewster angle. As is known in the art, where the incidence angle is smaller than or equal to the Brewster angle, the fastest path does not pass through bone 18, but is merely reflected from it.

First, V_{22} is measured. A signal is transmitted from transmitter 40 to transmitter/receiver 42 and its propagation time $T_{46} + T_{48}$ is measured. A second signal is transmitted from transmitter/receiver 42 to bone 18 and reflected back along a path segment 50. An isosceles triangle is formed by

(a) the line connecting transmitter 40 and transmitter/receiver 42, which has a length D_{4042};

(b) segment 46, which has a length D_{46}; and

(c) segment 48, which has a length D_{48},

Assuming that the thickness of tissue 22 is constant in the small region between transmitter 40 and transmitter/receiver 42, segment 50 has a length D_{50} which is equal to the height of the isosceles triangle.

If we assume that the average V_{22} is equal along segment 46, segment 48 and segment 50 then D_{46}, D_{48} and D_{50} are:

$$D_{46} = V_{22} * T_{46} \tag{13}$$

$$D_{48} = V_{22} * T_{48} \tag{14}$$

$$D_{50} = V_{22} * T_{50}/2 \tag{15}$$

Applying a known relationship between the sides and height of an isosceles triangle:

$$D_{4042} \div 2 = \sqrt{D_{48}{}^2 - D_{50}{}^2} \tag{16}$$

Solving equation 16 using equations 14 and 15 and using the equality between T_{48} and T_{46}:

$$D_{4042} = 2V_{22} * \sqrt{(T_{48}+T_{46})^2 - (T_{50})^2}/2 \tag{17}$$

However, T_{50}, T_{48} and D_{4042} are known thus:

$$V_{22} = D_{4042} \div \sqrt{(T_{48}+T_{46})^2 - T_{50}{}^2} \tag{18}$$

It should be noted that the above calculated V_{22} is an average along the actual path of the signal, i.e., including the weighted values of both the velocity in fat and the velocity in muscle tissue.

H_{44} is assumed to be equal to H_{40} (which is equal to D_{50}). Thus:

$$H_{44} = H_{40} = V_{22} * T_{50} \tag{19}$$

If a higher precision is required, or to reduce noise, V_{22} is calculated a second time using the signal propagation time between transmitter/receiver 42 and receiver 44 instead of the signal propagation time between transmitter 40 and transmitter/receiver 42. Of course, the distance between

transmitter/receiver 42 and receiver 44 is also such that the reflectance angle is smaller or equal to the Brewster angle. V_{22} is calculated by using the average of the first and second calculations.

Alternatively to the above described method of measuring V_{22}, H_{40} and H_{44}, other methods can be used. For example, H_{40} and H_{44} can be measured on an X-ray image or another medical image. V_{22} is then measured based on the signal propagation time of the reflection from bone 18.

Figs. 4A and 4B show a acoustic bone velocity measurement sensor according to another preferred embodiment of the present invention. A transmitter 70, a transmitter/receiver 72 and a receiver 74 are placed collinearly on soft tissue 22 which surrounds bone 18. As described above, the distance between transmitter 70 and transmitter/receiver 72 is such that a signal propagating from transmitter 70 to transmitter/receiver 72 does not pass through bone 18. Preferably, also the fastest path from transmitter/receiver 72 to receiver 74 does not pass through bone 18.

V_{22} and the thickness of soft tissue 22 in the region near transmitter/receiver 72 are then determined as described above. The acoustic velocity in bone 18 is then determined using the above described method of sending a signal from transmitter 70 to receiver 74. Preferably, the distance between transmitter 70 and transmitter/receiver 721 is such that a signal propagating between them is reflected at an angle R_{f1} which is approximately equal to the Brewster angle as shown in Fig. 4B. Thus, V_{22} is measured along the same path as that of the signal for measuring the bone velocity. Since the Brewster angle in human flesh is between 20° and 28°, an angle of 24° is a good estimate, which results in near overlap of the paths.

Preferably, transmitter/receiver 72 is midway between transmitter 70 and receiver 74. Thus, if the line connecting transmitter 70 and receiver 74 is not exactly parallel to bone 18, the fact that the thickness of the soft tissue is measured in between them will tend to give a close approximation to the

average velocities.

The minimal required distance of wave propagation in the bone using this method is approximately 2 to 3 millimeters. The distance between transmitter 70 and receiver 74 depends on the soft tissue thickness. Using this method, high resolution mapping of relatively uneven bones is possible. For example, such bones include the vertebra, the small bones in the wrist and portions of bone near joints. In addition, it is possible to measure the bone velocity in both longitudinal and transverse directions, since the length of the measured bone segment can be very short.

A preferred operating frequency is between 250 and 1500 kHz. It should be noted that since the distance that the signals travel in the bone are short, frequencies higher than those used in the prior art are practical, in spite of the higher attenuation of high frequency sound waves in bone. In general, higher frequencies give more precise results than do lower frequencies. In some preferred embodiments of the present invention, the operating frequency is preferably over 2 MHZ, more preferably, over 5 MHZ and in some preferred embodiments of the present invention, the preferred operating frequency is over 10 MHZ. Preferably, the wave is pulsed with a duration of between 2 and 150 microseconds.

The wave form used is preferably a single frequency pulsed wave, since the only aspect of the wave analyzed is the time of first reception of a signal. Alternatively, other, more complex wave forms or pulses are used and the received signals are analyzed.

Preferably, transmitter 70 and transmitter/receiver 72 are oriented to preferentially emit their signals at an angle which is the estimated Brewster angle, as known in the art. In addition, receiver 74 and transmitter/receiver 72 are preferably adapted to have a high gain for reception at the estimated Brewster angle.

Typically, when transmitter 70 and transmitter/receiver 72 are oriented at the Brewster angle, the sensor face is concave, rather than flat. Preferably, this concave space is

filled with a uniform material having a known acoustic velocity. In a preferred embodiment of the invention, the acoustic velocity of the filler material is close to that of soft tissue, thus, the effect of the filler material on the calculations described herein can be ignored. Alternatively, the effect of the layer of filler material on the acoustic velocity calculations can be estimated and taken into account, either during calibration or, as described below, as the effect of the top layer in a multi-layer structure.

It should be appreciated that the two steps of the above described process can be performed in either order and can also be performed simultaneously. Preferably, different frequencies are used for each signal. It should be appreciated that the ultrasound transmitter and receiver used typically has a very wide bandwidth. Thus, a plurality of wavelengths are emitted and each receiver processes its incoming signals to filter out and detect specific frequencies. Alternatively or additionally, the pulses are timed, so that no two pulses arrive tog ether at a single receiver.

Preferably, the transmitter 70, transmitter/receiver 72 and receiver 74 are controlled by a control unit 100. Thus, initiation of the above described signals, measurement of times, signal processing and velocity calculations are performed by control unit 100.

A three element sensor, such as described in reference to Fig. 4A and 4B, is preferably constructed to be less than 100 millimeters long, more preferably less than 50 millimeters long and in some preferred embodiments less than 3 millimeters long. In a specific preferred embodiment, the sensor is 32 millimeters long. The maximum distance allowed between such a sensor and a bone is approximately 2 centimeters. Due to the very high accuracy requirements from such a sensor, it is preferably constructed from a material which does not substantially expand or shrink in the temperature range of 15-40°C. Such materials typically comprise a mixture of a material which expands when heated from 15 to 40°C and a

material which shrinks when heated from 15 to 40°C.

It should be appreciated, that the distance between the ultrasonic elements can be optimized for a certain expected soft tissue depth. Thus, a typical operational system comprises several sensors, each suitable for a different range of depths. Alternatively, a single grid-type sensor, as described hereinbelow, is used.

Typically, the sensor is not constructed to have an exact distance between each ultrasonic element. Instead, a sensor is constructed with a precision of approximately 0.1 millimeter, and the exact distances between the elements are measured using a phantom. The results of the measurement, having a typical precision of over 2μ, are stored in controller 100 for use in the velocity determination as described in greater detail below. Such a phantom preferably comprises a plastic cylinder which has a cylindrical metal core with steps formed along its axis embedded within the plastic. Each step corresponds to a different known depth of the plastic overlying the metal core.

Bone acoustic velocity is typically not equal in different portions of the bone. Thus, to properly compare two bone acoustic velocity results from two different measuring sessions, the two measurements must be performed on the same portion of the bone. In particular, the location accuracy along the longitudinal axis of the bone should be on the order of 5 millimeters in long bones, such as the tibia. This accuracy is easy to attain using regular positioning methods, such as marking the location with permanent marker. However, the transverse positioning accuracy must be on the order of hundreds of microns. Since achieving this accuracy is difficult, the sensor is preferably mounted on a rocker such that transmitter 70, transmitter/receiver 72 and receiver 74 are along an axis of the rocker which is parallel to bone's 18 longitudinal axis. When measuring the bone acoustic velocity, the rocker is rocked in a transverse direction and a plurality of bone acoustic velocities are determined. The maximum or minimum determined value is used as the reference value for

comparison to bone acoustic velocity measurements during other sessions. Additionally or alternatively, the acoustic velocity of bone 18 is measured from several sides of bone 18, since the cortex of bone 18 typically has a number of different sectors, each of which has a different hardness and acoustic velocity.

It should be appreciated that with some bones, such as the vertebrae measuring the softer sectors is more practical than measuring the harder sectors, hence the search for the minimum velocity. The minimum determined velocity is typically in the softest sector. A minimum determined velocity found at a later date is also in the softest sector, thus, the velocity measurement is repeated at the same transverse location (same sector).

Additionally or alternatively, the acquired velocity measurements are used to build a transverse velocity profile of bone 18, which is useful for bone structure analysis.

Fig. 4C shows the embodiment described hereinabove with respect to Fig. 4A in a manner which will facilitate the following mathematical discussion. The purpose of this discussion is to analyze the mathematics of acoustic velocity determination in greater detail. Fig. 4C shows two possibilities, one in which the line connecting ultrasonic elements 70, 72 and 74 is parallel to bone 18 and, a second in which the line connecting ultrasonic elements 70, 72 and 74 is not parallel to bone 18. In each one of these cases the mathematical derivation of the ultrasonic bone velocity is different.

Figs. 4D and 4E show the times that are actually measured in the above described method. The equations which link these times to Fig. 4C, are as follows:

$$r1=\frac{AO+OB}{V_t} \tag{20}$$

$$\tau_2 = \frac{2h_2}{V_t} \quad (21)$$

$$\tau_3 = \frac{Cg + gD}{V_t} \quad (22)$$

$$\tau_0 = \frac{Az}{V_t} + \frac{zq}{V_B} + \frac{qD}{V_t} \quad (23)$$

In addition, γ is the Brewster angle. As used in the following equations, "a" is equal to the distance between points A and B (AB), b=BC and c=CD. In addition, the letter A, when not referring to the point A, refers to the sum of a+b+c, i.e., the shortest distance between transmitter 70 and receiver 74.

In a first, simplified case, which rarely occurs in practical situations, the fine connecting the ultrasonic elements 70, 72 and 74 is parallel to bone 18. Thus:

$$h_1 = h_2 = h_3 = h_4 \quad (24)$$

$$\text{Sin } \alpha = 0 \quad (25)$$

$$\tau_2 - \tau_3 \quad (26)$$

Soft tissue acoustic velocity V_{22} or V_2 is determined to be:

$$V_t = \frac{a}{\sqrt{\tau_1^2 - \tau_2^2}} \quad (27)$$

With bone acoustic velocity V_{18} or V_b determined by the following equation:

$$V_B^2 \times \left(\frac{\tau_0^2}{\tau_2^2} - 1 \right) - V_B \left(2 \frac{\tau_0}{\tau_2^2} A \right) + \left(\frac{A^2}{\tau_2^2} + V_1^2 \right) = 0 \qquad (28)$$

Solved as:

$$V_B = \frac{A}{\tau_0} \times \frac{1 \pm \frac{\tau_2}{\tau_0} \sqrt{1 - \frac{a^2}{A^2} \times \frac{\tau_0^2 - \tau_1^2}{\tau_1^2 - \tau_2^2}}}{1 - \frac{\tau_2^2}{\tau_0^2}} \qquad (29)$$

It should be noted, that in order to determine the bone acoustic velocity using the above described equations, not only does $h_1=h_2=h_3=h_4$ but also $\tau_1=\tau_3$. Due to variations in the acoustic velocity in soft tissue, resulting from soft tissue non-uniformities, this is rarely the case in *in vivo* measurements. However, one of the above mentioned two conditions can usually be met. In a preferred embodiment of the invention, the sensor is embedded in a rocker device. Such a rocker device is described in U.S. Patent 5,143,072, cited above. The rocker is rocked along an axis connecting transmitter 70 with transmitter/receiver 72 and receiver 74 and a plurality of measurements of soft tissue velocity and soft tissue thickness are performed. Bone velocity measurements are performed either when $h_1=h_2=h_3=h_4$ or when $\tau_1=\tau_3$.

A particular case in point is the acoustic velocity measurement of the femur. The surface geometry of the femur is not substantially flat in any portions thereof In addition, the thickness of the soft tissue overlying the femur is high, on the order of 6 cm. The bone acoustic velocity measurements are preferably performed when transmitter 70 and receiver 74 are both the same distance from the femur, to minimize false reflections.

When the line connecting ultrasonic elements 70, 72 and 74 is not parallel to bone 18, the following, more complex equations must usually be solved to determine the bone acoustic velocity. In the following equations, it is assumed that the configuration is similar to that (nonparallel)

configuration shown in Fig. 4C. If the configuration is a mirror image of that shown in Fig. 4C, h_2 should be measured at point C, and the equations modified accordingly.

Soft tissue acoustic velocity V_{22} or V_t is determined using the following equation:

$$V_t^4 \times \left[\left(\tau 3^2 - \tau 2^2 \right) + \frac{\left(\tau 1^2 - \tau 2^2 \right) \times \left(2b + c \right)}{a} + \frac{c^2 \times \left(\tau 1^2 - \tau 2^2 \right)^2}{4\tau 2^2 a} - \left(2b + c \right)^2 \times \frac{\left(\tau 1^2 - \tau 2^2 \right)^2}{4\tau 2^2 a^2} \right] +$$
$$+ V_t^2 \times \left[\frac{\left(2b + c \right)^2 \times \left(\tau 1^2 - \tau 2^2 \right)}{2\tau 2^2} - a \times \left(2b + c \right) - \frac{c^2 \times \left(\tau 1^2 - \tau 2^2 \right)}{2\tau 2^2} - c^2 \right] +$$
$$+ \frac{a^2 c^2}{4\tau 2^2} - \left(2b + c \right)^2 \times \frac{a^2}{4\tau 2^2} = 0 \qquad (30)$$

Bone acoustic velocity is determined using an equation similar to equation (28):

$$p_1 V_B^4 + p_2 V_B^3 + p_3 V_B^2 + p_4 V_B + p_5 = 0 \qquad (31)$$

Where:

$$p_1 = \tau 0^2 - \left(\tau 2 + \frac{b + c - a}{V_t} \times Sin\alpha \right)^2 \qquad (32)$$

$$p_2 = -2\tau_0 A Cos\alpha \qquad (33)$$

$$p_3 = A^2 Cos^2 \alpha - V_t^2 \times \left[\tau_0^2 - 2 \left(\tau_2 + \frac{b + c - a}{V_t} \times Sin\alpha \right)^2 \right] \qquad (34)$$

$$p_4 = 2\tau_0 A V_t^2 Cos\alpha \qquad (35)$$

$$P_5 = -V_t^2 \times \left[A^2 Cos^2 \alpha + \left(V_t \tau_2 + (b - c - a) \times Sin\alpha \right)^2 \right] \quad (36)$$

$$Sin\alpha = \frac{a^2 - V_t^2 \left(\tau_1^2 - \tau_2^2 \right)}{2 V_t \tau_2 a} \quad (37)$$

The exact length of the different path segments in bone 18 and in soft tissue 22 can be determined using the geometrical relationships shown in Fig. 4C and the above-determined soft tissue and bone velocity. In particular, the path of the wave from transmitter 70 to receiver 74 is:

$$z'q' = (a+b+c) Cos\alpha - \tau_2 V_t \frac{Sin\gamma}{Cos\gamma} - (b+c-a) Sin\alpha \frac{Sin\gamma}{Cos\gamma} \quad (38)$$

$$A'z' = \frac{\tau_2 V_t - 2a Sin\alpha}{2 Cos\gamma} \quad (39)$$

$$D'q' = \frac{\frac{\tau_2 V_t}{2} + (b+c) \times Sin\alpha}{Cos\gamma} \quad (40)$$

Figs. 5A and 5B show an additional embodiment of the present invention. Acoustic bone velocity is measured using the above described method of measuring the travel time of a signal emitted by a transmitter 80 until it is first received by a receiver 86. However, this embodiment differs from the embodiment of Figs. 4A and 4B in that a pair of transmitter/receivers 82 and 84 are used in place of the single transmitter/receiver 72. This change has two main benefits. First, the thickness of tissue 22 and the acoustic velocity in tissue 22 are measured in more than one location. Thus, body areas having uneven surfaces or varying acoustic

soft tissue velocity are recognized. Preferably, the operator is alerted and he takes appropriate action, such as changing the measured location. Alternatively, acoustic velocity calculations are corrected for these differences.

Second, transmitter/receiver 82 can be located independently of transmitter/receiver 84. In the embodiment of Figs. 4A and 4B, a prefer-red situation was described wherein the path of the signals used for acoustic soft tissue velocity determination coincide with the path used for acoustic bone velocity determination. In the present embodiment, transmitter/receiver 82 can be positioned relative to transmitter 80 so that this preferred situation occurs (in the method described below with respect to Fig. 5B). Transmitter/receiver 84 is positioned in a similar manner relative to receiver 86. It should be noted that the distance between transmitter 80 and receiver 86 does not adversely effect the measurement in a substantial manner.

Figs. 5A and 5B describe a two step process wherein some measurements are taken in the first step, and some in the second. However, the order of these steps does not matter and preferably the two steps are performed simultaneously using different frequencies or wave forms. If a two step method is used, the acoustic bone velocity determination is preferably performed in both steps.

However, performing only one of these two steps is sufficient in determining the bone acoustic velocity. Preferably, the decision which step to perform is made based on the configuration of transmitter/receiver 82, transmitter/receiver 84, transmitter 80, receiver 86 and bone 18, which affects the relative locations of the soft tissue velocity measurement and the bone velocity measurement.

In the step described in Fig. 5A, acoustic bone velocity is measured by measuring the travel time of a signal between transmitter 80 and receiver 86. In addition the following measurements useful for soft tissue velocity determination are performed:

(a) the thickness of tissue 22 under

transmitter/receiver 82;

(b) the thickness of tissue 22 under transmitter/receiver 84; and

(c) the travel time of a signal from transmitter/receiver 82 to transmitter/receiver 84.

These measurements are sufficient for acoustic soft tissue velocity determination and for determination of changes in the thickness of tissue 22. It should be noted that if transmitter/receiver 82 and transmitter/receiver 84 are far enough apart such that a signal from transmitter/receiver 82 to transmitter/receiver 84 passes through bone 18, measurement (c) is not performed. However, measurements (c) and (d), performed in the step of Fig. 5B compensate for not making measurement (c).

In the step shown in Fig. 5B, acoustic bone velocity is measured by measuring the travel time of a signal between transmitter 80 and receiver 86. In addition the following measurements useful for soft tissue velocity determination are performed:

(a) the thickness of tissue 22 under transmitter/receiver 82;

(b) the thickness of tissue 22 under transmitter/receiver 84,

(c) the travel time of a signal from transmitter 80 to transmitter/receiver 82; and

(d) the travel time of a signal from transmitter/receiver 84 to receiver 86.

These measurements are sufficient for acoustic soft tissue velocity determination and for determination of changes in the thickness of tissue 22. Again, if the fastest path for a signal from transmitter 80 to transmitter/receiver 82 or from transmitter/receiver 84 to receiver 86 is through bone 18, measurement (c) and/or (d) are not performed. However, measurement (c) performed in the step of Fig. 5A compensates for these missed measurements.

It should be noted that the measurements performed in the step shown in Fig. 5B determine the acoustic soft tissue

velocity in local regions surrounding the regions wherein the signal used for acoustic bone velocity determination travels. Thus, this embodiment is suitable for acoustic bone velocity determination in cases where the surface is known to be uneven or acoustic soft tissue velocity is known to vary. In addition, acoustic bone velocity determination is possible in over curved body parts, such as along a transverse axis of bone 18, due to the short path segment necessary along bone 18.

The small dimensions of the minimally required bone path segment make it possible to scan with a high spatial resolution, using embodiments of the present invention. For example, to measure the acoustic velocity in a portion of the cortex of a tooth, a 10 MHZ ultrasonic pulse can be used. Due to the high frequency of the ultrasound, the sensor dimensions can be in the order of 3 millimeters and the resolution better than 1 millimeters.

Figs. 6A and 6B show another preferred embodiment using three transmitter/receivers, a transmitter and a receiver. As before, acoustic bone velocity is determined by measuring the travel time of a signal emitted by a transmitter 90 to a receiver 98. A two step process of acoustic soft tissue velocity determination is preferred.

Fig. 6A shows a first step, wherein the following measurements are performed:

(a) transmission time from transmitter 90 to a transmitter/receiver 92;

(b) transmission time from transmitter/receiver 92 to a transmitter/receiver 96;

(c) transmission time from transmitter/receiver 96 to receiver 98;

(d) the thickness of tissue 22 underlying a transmitter/receiver 94; and

(e) transmission time from transmitter 90 to receiver 98.

Fig. 6B shows a second step, wherein the following measurements are performed:

(a) transmission time from transmitter/receiver 92 to transmitter/receiver 96;

(b) the thickness of tissue 22 underlying transmitter/receiver 92;

(c) the thickness of tissue 22 underlying transmitter/receiver 94;

(d) the thickness of tissue 22 underlying transmitter/receiver 96; and

(e) transmission time from transmitter 90 to receiver 98,

Thus, the thickness of tissue 22 is measured at three locations so that changes in the thickness of tissue 22 are easier to incorporate in the calculation.

Preferably, transmitter/receivers 92 and 96 are arranged so that they measure the thickness of tissue 22 at the exact point wherein it is estimated that the acoustic bone velocity determination signal enters and leaves the bone. Transmitter/receiver 94 is preferably arranged so that it measures the thickness of tissue 22 at the estimated point of reflections for signals from transmitter/receiver 92 to transmitter/receiver 96. Thus, a more precise estimate of the signal path length in tissue 22 is possible.

Figs. 7A and 7B show yet another preferred embodiment of the present invention. As before, bone acoustic velocity is determined by measuring the travel time of a signal from a transmitter 110 to a receiver 120. However, a plurality of four transmitter/receivers 112, 114, 116 and 118 are used to measure the soft tissue acoustic velocity. Ms embodiment incorporates several features described in previous embodiments, and specifically shown in Fig. 7B:

(a) soft tissue acoustic velocity is determined separately for each area where the signal travels through tissue 22;

(b) the thickness of tissue 22 is measured at the point where the signal enters bone 18; and

(c) the path of the signal coincides with the path used by signals for measuring the soft tissue acoustic velocity.

As can be appreciated, to achieve all of the above mentioned features, the transmitter/receivers are preferably located as shown in Fig. 7B and not as shown in Fig. 7A.

Preferably two independent measurements processes are performed. A first process, performed in the region near transmitter 110 is:

(a) measuring the travel time for a signal from transmitter 110 to transmitter/receiver 114 (transmitter/receiver 114 need only be a receiver);

(b) measuring the thickness of tissue 22 underlying transmitter/receiver 112; and

(c) calculating the thickness of tissue 22 and its acoustic velocity in the region near transmitter 110 using (a) and (b).

The second process is very similar, and is performed in the region near receiver 120: (a) measuring the travel time for a signal from transmitter/receiver 16 to receiver 120 (transmitter/receiver 116 need only be a transmitter);

(b) measuring the thickness of tissue 22 underlying transmitter/receiver 118; and

(c) calculating the thickness of tissue 22 and its acoustic velocity in the region near receiver 120 using (a) and (b).

In the embodiments shown in Figs 4A-7B, all the ultrasonic elements are preferably collinear. However, the correct acoustic velocities can be determined if the ultrasonic elements are not collinear but the distances between the acoustic elements are known.

In the above described embodiments, a transmitter/receiver, such as transmitter/receiver 82 (Fig. 5A), both transmits and receives an ultrasonic wave. The inventor has found that the reception quality of an ultrasonic transmitter receiver is degraded for a short time after transmitting an ultrasonic wave. The measured received signal is the sum of the actual received signal and a transmission signal residue. This degradation can be prevented by separating transmitter/receivers into a pair of a transmitter

and a receiver.

Figs. 8A and 8B shows such a separation performed on the embodiments shown in Figs. 7A and 7B. In Fig. 8A, a transmitter 130 corresponds to transmitter 110 (in Fig. 7A), a transmitter 132 and a receiver 134 correspond to transmitter/receiver 112, a receiver 136 corresponds to receiver 114, a transmitter 138 corresponds to transmitter 116, a transmitter 140 and a receiver 142 correspond to transmitter/receiver 118 and a receiver 144 corresponds to receiver 120. The method of operation is as described above in reference to Fig. 7A, excepting the thickness underneath transmitter/receiver 112 and 118 which are measured using a transmitter and a receiver instead of a transmitter/receiver. Measuring the thickness of soft tissue 22 using a transmitter and a receiver is as accurate as when using a single transmitter/receiver because the distance between the transmitter and the receiver (i.e., the distance between transmitter 132 and receiver 134) is much shorter than the thickness of soft tissue 22. In addition, the surface of bone 18 is sometimes irregular. When the reflection point of the wave from transmitter 112 is different from that of the wave from transmitter 110 to receiver 114, due to these irregularities, the soft tissue velocity determination is incorrect. The wave from transmitter 132 to receiver 134 travels at an angle, thus, the irregularities have a smaller effect on the reflection point.

Fig. 8B shows another alternative measuring method wherein transmitter/receivers are used, however, there is a large time differential between the transmitting and the receiving, so the reception quality is not degraded.

For the configuration of Fig. 8B a plurality of measurement steps are performed, including:

(a) measuring the signal propagation time from a transmitter 150 to a transmitter/receiver 156;

(b) measuring the signal propagation time from a transmitter/receiver 152 to a receiver 164;

(c) measuring the signal propagation time from a

transmitter 154 to transmitter/receiver 152;

(d) measuring the signal propagation time from transmitter/receiver 156 to receiver 160; and

(e) measuring the wave propagation time between transmitter 150 and receiver 164.

The acoustic bone velocity of bone 18 is determined as described hereinabove. It should be appreciated that the measurement steps may be performed simultaneously, however, preferably, transmitter/receivers do not transmit waves shortly before they are supposed to receive waves.

Another embodiment of the device and method according to the present invention is shown in Fig. 8C. In particular, the device includes two transducers situated on the surface of the body (e.g., the skin 20). One of these transducers is an ultrasonic transmitter 201 and the other transducer is an ultrasonic receiver 202. As in the embodiments according to the present invention described above, the surface on which these transducers are situated is separated from an outer surface of the bone 18 by a layer of soft tissue 22.

In limited situations, a thickness h of the soft tissue 22 between the transmitter 201 and the receiver 202 is uniform (the skin 20 extends parallel to the outer layer of the bone 18). In most cases, however, the thickness h of the soft tissue 22 between the transmitter 201 and the receiver 202 is not uniform (i.e., the skin not extending parallel to the surface of the bone 18). Generally, the skin 20 extends at an angle of φ with respect to the surface of the bone 18. Before the transmitter 201 and the receiver are situated on the skin 20, an acoustic grease may be applied to the skin 20. This acoustic grease facilitates a substantially uninhibited acoustic wave propagation (generated by the transmitter 201) through the skin 20.

The transmitter 201 may be positioned at a transmitter position 205' on the skin 20, and the receiver 202 may be situated at a receiver position 209' on the skin 20. In operation, the transmitter 201 transmits an ultrasound signal in a form of an acoustic wave, which can propagate as

described below. The following situations are usually encountered when utilizing the transmitters and receivers according to the present invention:

A. Acoustic Wave propagate only via Surface of Skin

In this instance, the wave travels through the soft tissue 22 from the transmitter position 205' to the receiver position 209' along the acoustic grease at the surface layer of the skin 20. The acoustic wave travels through the soft tissue 22 at a first acoustic velocity V_S, which is approximately 1540 m/s. It is one of the objects of the present invention, however, to determine a second acoustic velocity V_B of the acoustic wave propagating along the surface of the bone 18.

As indicated for above-described embodiments, a Critical angle (e.g., the Brewster angle as described above) γ is defined by the expression:

$$\sin \gamma = \frac{V_S}{V_B}, \tag{41}$$

where $V_B > V_S$.

The time for propagating the acoustic wave from the transmitter 201 (i.e., from the transmitter position 205') to the receiver position 209' along the skin 20 (and via the acoustic grease) is determined in the following expression:

$$T_{205'-209'} = \frac{A_{205'-209'}}{V_S}, \tag{42}$$

where $A_{205'-209'}$ equals to an axial distance of the bone 18 between the transmitter 201 and the receiver 202.

B. Acoustic Wave propagate from Transmitter to Receiver by reflecting from Bone

In this instance (and as described above with respect to embodiments illustrated in Figs. 3-8B), the wave travels from

the transmitter position 205', through the soft tissue 22, deflected from the surface of the bone 18 at a reflection position 210' to reach the receiver 202 at the receiver position 209'.

The time for propagating the acoustic wave from the transmitter position 205' to the receiver position 209' deflected at the reflection position 210' is determined using the following expression:

$$T_{205'-210'-209'} = \frac{A_{205'-210'-209'}}{V_s} \quad (43)$$

where $A_{205'-210'-209'}$ is a distance from the transmitter 201 to the reflected position 210', and then to the receiver 202. The distance $A_{205'-210'-209'}$ depends on the thickness h of the soft tissue 22 and an angle φ formed between the axial direction of the surface of the bone 18 and an extension between the transmitter 201 and the receiver 202. Accordingly $T_{205'-210'-209'} > T_{205'-209'}$.

C. Acoustic Wave propagate from Transmitter, through Soft Tissue, along the surface of Bone and to Receiver

In this instance (and as also described above with respect to embodiments illustrated in Figs. 3-8B), the wave travels through the soft tissue 22 from the transmitter position 205' to reach a first position 206' at the surface of the bone 18; the wave is the refracted at a surface of the bone 18 at the Critical angle γ (as described above) with respect to a perpendicular line to the surface of the bone 18, propagates along the surface of the bone 18 from the first position 206' to a second position 207', and then travels through the soft tissue 22 at the same Critical angle with respect to the perpendicular line to the surface of the bone 18 for reaching the receiver 202 at the receiver position 209'.

To obtain the wave's estimated time of travel from the

transmitter position 205′ to the first position 206′, to the second position 207′, and finally reach the receiver position 209′ (i.e., T_{total}), it is preferable to add the following times:

$T_{205'-206'}$ - the time that the wave travels (in the soft tissue 22) from the transmitter position 205′ to the first position 206′;

$T_{206'-207'}$ - the time that the wave propagates (or spreads) along the surface of the bone 18 from the first position 206′ to the second position 207′; and

$T_{207'-209'}$ - the time that the wave travels (in the soft tissue 22) from the second position 207′ to the receiver position 209′.

Accordingly, T_{total} is calculated using the following formula:

$$T_{total} = T_{205'-206'} + T_{206'-207'} + T_{207'-209'} \quad (44)$$

Since the horizontal distance (i.e. along an axis parallel to the surface of the bone 18) is annotated as $A_{212'-213'}$, the vertical component of the distance $A_{205'-211'}$ between the transmitter position 205′ and the first position (i.e., $A_{205'-206'}$), and the vertical component $A_{205'-212'}$ of half of the distance between the transmitter position 205′ and the receiver position 209′ (i.e., $A_{205'-209'}$ / 2) can be determined using the following formulas:

$$A_{205'-211'} = \frac{A_{212'-213'}}{2} \sin\varphi \qquad A_{205'-212'} = h - \frac{A_{212'-213'}}{2} \sin\varphi \quad (45)$$

where φ is an angle formed between the axial direction of the surface of the bone 18 and an extension between the transmitter 201 and the receiver 202 (as described above), and

h is the height from the bone 18 to an imaginary line parallel to the surface of the bone 18 and extending between positions 212′ and 213′.

The distance between the transmitter position 205' and the first position 206' (i.e., $A_{205'-206'}$) is determined using the following formula:

$$A_{205'-206'} = \frac{h - \frac{A_{212'-213'}}{2} \sin\varphi}{\cos\gamma} \quad (46)$$

where γ is the Critical angle (described above). Accordingly, $T_{205'-206'}$ can be determined using the following formula:

$$T_{205'-206'} = \frac{h - \frac{A_{212'-213'}}{2} \sin\varphi}{V_s . \cos\gamma} \quad (47)$$

$T_{207'-209'}$ can be determined using the following formula:

$$T_{207'-209'} = h + \frac{\frac{A_{212'-213'}}{2} \sin\varphi}{V_s . \cos\gamma} \quad (48)$$

and $T_{206'-207'}$ is calculated according to the following formula:

$$T_{206'-207'} = \frac{A_{212'-213'}}{V_B} \cos\varphi - \frac{2h\tan(\gamma)}{V_B} \quad (49)$$

Therefore, T_{total} can be calculated according to the following:

$$T_{total} = \frac{2h \cos\gamma}{V_s} + \frac{A_{212'-213'}}{V_B} \cos\gamma. \quad (50)$$

Using the above formulas, V_s can then be determined.

A further embodiment of the device according to the present invention is shown in Fig. 8D. The device includes a probe 250 which encloses two transmitters 251, 252 (i.e., piezo-sensing elements) and two receivers 253, 254 (i.e., also piezo-sensing elements). Each of the transmitters 251, 252 functions substantially in the same manner as the transmitter 201 discussed above and shown in Fig. 8C. In addition, each of the receivers 253, 254 functions substantially in the same manner as the receiver 202 (shown in Fig. 8C). The device also includes a first high-voltage short-impulse driver 256a coupled to the first transmitter 251, and a second high-voltage short-impulse driver 256b coupled to the second transmitter 252. The device further includes first and second signal processors 257a, 257b, and a controller 258. Each of the signal processors 257a, 257b preferably includes an amplifier and a transforming device. The first signal processor 257a is coupled to the first receiver 253, and the second signal processor 257b is coupled to the second receiver 254. The controller 258 is coupled to the first and second high-voltage short-impulse driver 256a, 256b, and to the first and second signal processors 257a, 257b. The controller 258 regulates the transmission, reception and preliminary processing of acoustic impulses (e.g., acoustic waves). A computing device 259 is coupled to the controller 258 for further processing of information received from the controller 258. The computer 259 also stores selected information a local database (not illustrated) or provide this information to a remote database via wired communication means (e.g., local area network, T1 line, etc.) or wireless communication means (e.g., cellular telephone communication signals).

The process utilized by the device according to the present invention is described below. As a preliminary step for the process, an acoustic grease (e.g., a silicon oil) is applied to the surface of the skin 20. The probe 250 is then positioned on the acoustic grease. The process according to this embodiment of the present invention is initiated by the controller 258, which generates a first short synchronous

pulse (having a wavelength of about 20 nanoseconds). This pulse (or the acoustic wave) is conditioned by the first high-voltage short-impulse driver 256a to acquire an amplitude of approximately 300 Volts. The pulse then reaches the first transmitter 251, which generates a mechanical ultrasound oscillation short pulse in response to the pulse received from the first high-voltage short-impulse driver 256a. The frequency spectrum of oscillations of the short pulse generated by the first transmitter 251 is preferably determined by, e.g., a thickness of the piezo-plate of the first transmitter 251. The spectrum of the frequencies of these oscillations is preferably between 100 kHz to 20 MHZ.

The short pulse generated by the first transmitter 251 can spread in various directions, however the most high-speed route of the short pulse (and as indicated above with respect to Figs. 2-8B) is a route of the short pulse through the soft tissue 22 at the Critical angle (as described above). The pulse bends at the surface of the bone 18 to travel along this surface, and then further bends at the surface of the bone 18 (at the Critical angle with respect to the surface of the bone 18) to propagate through the soft tissue 22 and reach the first receiver 253 and/or the second receiver 254. The above-described process is also utilized to generate a short pulse via the second transmitter 253. This pulse would also propagate through the soft tissue 22, along the surface of the bone 18 to reach the first transmitter 253 and the second transmitter 254.

An exemplary embodiment of the device according to the present invention first measures the time $T_{251-253}$ that the pulse travels from the first transmitter 251 (through the soft tissue 22, diffracted at the Critical angle γ - at a first point 271 - to propagate along the surface of the bone 18, and again diffracted at the Critical angle - at a third point 273 - to travel through the soft tissue 22) to reach the first receiver 253. For identification purposes, the path from the first transmitter 251 to the first receiver 253 shall be referred to $Path_{251-253}$. The mechanical oscillations of the

pulse are provided by the first driver 256a (actuated by the controller 258) and converted by the first receiver 253 into electrical oscillations. These electrical oscillations are amplified and transformed into a digital form to be stored by the first signal processor 257a in a storage device (e.g., hard disk, RAM, etc.). In addition, the digitized electrical oscillation information is provided the controller 258, which routes this information to the computer 259. The computer 259 generates the following formula:

$$V_B \cdot T_{251\text{-}253} - \frac{2K_1}{\tan(\gamma)} = A_{251\text{-}253} \cdot \cos\varphi \qquad (51)$$

where:

$$K_1 = h - \frac{A_{251\text{-}254} - A_{251\text{-}253}}{2} \cdot \sin\varphi$$

$A_{251\text{-}254}$ is a distance between the first transmitter 251 and the second receiver 254; and

$A_{251\text{-}253}$ is a distance between the first transmitter 251 and the first receiver 253.

In addition, the second transmitter 252 receives mechanical oscillations from the second driver 256b to be converted into the electrical oscillations (in a similar manner as described above with respect to $Path_{251\text{-}253}$). In particular, the pulse is transmitted from the second transmitter 252, via the soft tissue 22, refracted at a second point 272 - at the Critical angle γ -, travels along the surface of the bone 18, refracted again at a fourth point 274 - at the Critical angle γ - to propagate through the soft tissue 22, to reach the second receiver 254. For identification purposes, the path from the second transmitter 252 to the second receiver 254 shall be referred to $Path_{252\text{-}254}$. The device and method according to the present invention measures the time $T_{252\text{-}254}$ that the pulse propagates via $Path_{252\text{-}254}$. In particular, the second driver 256b provides mechanic oscillations (i.e., the pulse) to the second transmitter 252, which transmits this pulse to the second

receiver 254 via $Path_{252-254}$. The mechanical oscillations are again converted into electrical signals and provided to the computer 259 via the second signal processor 257b. The computer 259 then generates the following formula:

$$V_B \cdot T_{252-254} - \frac{2K_2}{\tan(\gamma)} = A_{252-254} \cdot \cos\varphi \quad (52)$$

where:

$$K_2 = h + \frac{A_{251-254} - A_{252-254}}{2} \cdot \sin\varphi$$

and $A_{252-254}$ is a distance between the second transmitter 252 and the second receiver 254.

The device and method according to the present invention also measures the time $T_{251-254}$ that the pulse travels from the first transmitter 251 to the second receiver 254 (via the soft tissue 22, refracted at the first point 271 - at the Critical angle γ -, travels along the surface of the bone 18, refracted again at the fourth point 274 - at the Critical angle γ - to propagate through the soft tissue 22). This path is identified as $Path_{251-254}$. The computer measures $T_{251-254}$ and generates the following formula:

$$V_B \cdot T_{251-254} - \frac{2h}{\tan(\gamma)} = A_{251-254} \cdot \cos\varphi \quad (53)$$

where $A_{251-254}$ is a distance between the first transmitter 251 and the second receiver 254.

The device and method according to the present invention can also measure the time $T_{252-253}$ that the pulse travels from the second transmitter 252 to the first receiver 253 (via the soft tissue 22, refracted at the second point 272 - at the Critical angle γ -, travels along the surface of the bone 18, refracted again at the third point 273 - at the Critical angle γ - to propagate through the soft tissue 22). This path is identified as $Path_{252-253}$. The computer measures $T_{252-253}$ and

generates the following formula:

$$V_B \cdot T_{252\text{-}253} - \frac{2h}{\tan(\gamma)} = (A_{251\text{-}253} + A_{252\text{-}254} - A_{251\text{-}254}) \cdot \cos\varphi \quad (54)$$

where $A_{251\text{-}254}$ is a distance between the first transmitter 251 and the second receiver 254.

Using the device and method according to the present invention, the velocity V_B along the surface of the bone 18, the height h between the surface of the bone 22 and an imaginary line (which is parallel to the surface of the bone 18 and which extends, e.g., through a midpoint between the first transmitter 251 and the second receiver 254), and angle φ which is an angle formed between the axial direction of the surface of the bone 18 and an extension between the transmitters 251, 252 and the receivers 253, 254 are unknown. Accordingly, three equations are used (i.e., equations (51), (52), and (53)) to solve for three unknowns (i.e., V_B, h, and φ), assuming that the velocity V_S of the pulse through the soft tissue 22 is 1540 m/s. In addition, it is possible to utilize the above described formula (54) for $Path_{252\text{-}253}$ to determine an exact value for the velocity V_S of the pulse in soft tissue 22. Therefore, four equations are used (i.e., equations (51), (52), (53), and (54)) to solve for four unknowns (i.e., V_B, V_S, h, and φ).

Solving the equations (51), (52), (52), and (54) yields the following result for the height h:

$$h = \frac{V_B \cdot T_{251\text{-}254} \cdot \tan(\gamma)}{2} - \frac{A_0 \cdot \tan(\gamma)}{2} \cdot \cos\varphi \quad (55)$$

Then, the angle φ can be obtained by inserting the equation (55) into the equations (51), (52), (53), and (54):

$$\cos\varphi = \frac{V_B \cdot (T_{252\text{-}253} - T_{251\text{-}254})}{2A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254}} \quad (56)$$

By inserting the solved variables (i.e., h and φ)into two of

the equations (51), (52), 53 and (54), the following formulas are provided:

$$V_B \cdot (T_{251\text{-}253} - T_{251\text{-}254}) + (A_{251\text{-}254} - A_{251\text{-}253}) + \frac{V_B (T_{252\text{-}253} - T_{251\text{-}254})}{2A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254}} + \frac{A_{251\text{-}254} - A_{251\text{-}253}}{t_g Y} \sqrt{1 - \frac{V_B^2 (T_{252\text{-}253} - T_{251\text{-}254})^2}{(2 \cdot A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254})^2}} = 0 \quad (57$$

$$V_B \cdot (T_{252\text{-}254} - T_{251\text{-}254}) + (A_{251\text{-}254} - A_{252\text{-}254}) + \frac{V_B (T_{252\text{-}253} - T_{251\text{-}254})}{2 \cdot A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254}} + \frac{A_{251\text{-}254} - A_{252\text{-}254}}{t_g Y} \sqrt{1 - \frac{V_B^2 (T_{252\text{-}253} - T_{251\text{-}254})^2}{(2 \cdot A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254})^2}} = 0 \quad (58)$$

From the equation (57), V_S (the velocity of the pulse in the soft tissue 22) is determined as a function of V_B (the velocity of the pulse at the surface of the bone 18):

$$V_S^2 = \frac{(A_{251\text{-}254} - A_{251\text{-}253})^2}{\frac{(A_{251\text{-}254} - A_{251\text{-}253})^2}{V_B^2} + M} - \frac{V_B^2}{\frac{(A_{251\text{-}254} - A_{251\text{-}253})^2}{V_B^2} + M} + \frac{(A_{251\text{-}254} - A_{251\text{-}253})^2 \cdot (T_{252\text{-}253} - T_{251\text{-}254})^2}{(2A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254})^2} \quad (59$$

where:

$$1 = \left[(T_{251\text{-}254} - T_{251\text{-}253}) - \frac{(A_{251\text{-}254} - A_{251\text{-}253})(T_{252\text{-}253} - T_{251\text{-}254})}{2 \cdot A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254}} \right]^2 - \frac{(A_{251\text{-}254} - A_{251\text{-}253})^2 \cdot (T_{252\text{-}253} - T_{251\text{-}254})^2}{(2 \cdot A_{251\text{-}254} - A_{251\text{-}253} - A_{252\text{-}254})^2} \quad (60$$

From the equation (58), V_B (the velocity of the pulse traveling along the surface of the bone 18) can be determined.

When the acoustic grease accommodating a low velocity for a pulse (e.g., silicone oil having a speed of approximately 1020 m/s) is applied on the surface of the skin 20, it is also possible to measure the velocity of the soft tissue 22 (i.e., V_S). By changing the frequency of the pulse, it is possible, according to the present invention, to penetrate the soft

tissue 22 with the pulse at a predetermined depth. As such, the velocity of the pulse in a specific layer in the soft tissue 22 (e.g., skin 20, hypodermic layer, etc.) can be determined. In particular, this layer to be measured should have a denser composition than the layers of the soft tissue 22 through which the pulse must travel. Accordingly, the device and method according to the present invention can be used in the fields of dermatology, diabetes diagnostics, endocrinology (e.g., diabetes diagnostics) and in other branches of medicine. Particularly, it is possible to measure the velocity in layers of soft tissue 22 by decreasing the distances between the transmitters 251, 252 and the receivers 253, 254 so that the pulse does not reach the surface of the bone 18 (or only reflect from the surface of the bone 18). Thus, the pulse transmitted by the first and second transmitters 251, 252 are propagated only in the soft tissue 22, and the required velocity determination can be made.

In addition, these pulses may be propagated along the skin 22 in the soft tissue 22 (for example, the mineral oil having the velocity of about 100 m/s) while excluding the velocity measurement of the pulse traveling in the acoustic grease. The pulse transmitted through the acoustic grease and diffracted at the Critical angle γ into the soft tissue 22 spreads travels in the particular layer of the soft tissue 22 has a thickness of about the wave-length $\lambda = c/f$, where c is the ultrasound velocity in the soft tissue 22 (in m/s), and f is the frequency (in Hz). For example, when the frequency is approximately 1 MHZ and the velocity in the soft tissue 22 is approximately 1500 m/s, the thickness of the layer (of the soft tissue 22) in which the measuring is made is approximately between 1.5 and 2.0 mm. If the frequency is modified, it is also possible to change the thickness of the measured layer. By changing the frequency, it is possible to analyze the structure of the skin 22 and hypodermic layers of the soft tissue 22.

It is known that the velocity of ultrasound in a purely cortical bone is approximately 3000 m/s - 4700 m/s (which

corresponds to the Critical angle of approximately 19° - 31°), and the velocity in trabecular bones with a thin surface layer of cortical bone is approximately 1650 m/s - 3000 m/s (which corresponds to the Critical angle γ of approximately 31° - 69°). As such, in order to increase the efficiency of each transmitter and/or receiver, each transmitter and receiver can be a linear phasable multi-element grid element. Accordingly, using these elements, it is possible to focus the transmission and the reception of the pulse by positioning these elements in optimal positions.

It is also possible to provide additional transmitters and/or corresponding receivers to determine velocities in different layers of the soft tissue. As described above, the velocity in the soft tissue 22 can be determined by measuring the time of a fourth pulse and solving the equations above for the velocity in the soft tissue 22. Accordingly, if a fifth pulse is transmitted by another transmitter and received by one of the receivers (or a further receiver), the time of propagation of this fifth pulse is measured, and thus another determination can be made for a velocity in a further layer of the soft tissue 22. Thus, it is possible to determine the velocity of a pulse in, e.g., a layer of fat tissue and in a layer of muscle tissue.

In addition, it is also possible to determine the velocity in the soft tissue 22 using the methods and devices shown in Figs. 13A and 13B (and described below), and to determine the velocity V_s via the surface of the bone 22 using the device and methods shown in Figs. 8C and 8D (described above). These determinations can be made using the computer 259 either simultaneously or at a predetermined time interval. The computer 259 can determine with procedure and/or method to utilize for determining the requisite velocity.

In a further embodiment according to the present invention, it is possible to calibrate the probe 250 by accurately measuring the distances between the first transmitter 251, the second transmitter 252, the first receiver 253 and/or the second receiver 254 for each probe

250. These distance can be accurately measured by attaching the probe to a "phantom", which is a flat material of having a known propagation of a speed of sound. In particular, the transmitters 251, 252 generate a signal, while the receivers 253, 254 receive each of the pulses (as described above). Since the Critical angle γ is zero (since the material has a flat surface), and since the velocity through the "phantom" is known, the remaining unknowns are the distance between the first transmitter 251 and the second transmitter 252, and the distance between the first receiver 253 and the second receiver 254. The equations described above are thus solve to obtain these distances. Accordingly, the probe 250 is thus calibrated.

These calculated distances (i.e. calibrated parameters) are then stored by the computer 259 into a Read Only storage device (e.g., a FLASH ROM). This Read Only storage device is either coupled to the probe 250 or incorporated in the probe 250, so that the calibration of this particular probe 250 is provided on its own Read Only storage device. Once the probe 250 is coupled to a measuring system (via the drivers 256a, 256b and the signal processors 257a, 257b), the calibration parameters of the probe 250 are retrieved by the measuring system and are utilized to measure velocity V_B. It is preferable to calibrate each probe in such manner because the distances between the transmitters 251, 252 and between the receivers 253, 254 may differ in each probe. Accordingly, this calibration would improve the determination of the velocity V_B along (i.e., below) the surface of the bone, by obtaining the exact distances between the transmitters and the receivers, which are necessary for the above-described formulas.

In a further embodiment according to the present invention, the measuring system described above can also connect to a plurality of probes at the same time. Even though the probes are simultaneously operated, the measuring system can identify each probe as a function of the calibration parameters that are stored on each respective Read

Only storage device, which may further store an identification code for the respective probe. Furthermore, since each probe may operate on a distinct channel and may have different time delays, each probe can therefore be calibrated such that these delays are measured and stored into the Read Only storage device. This delay information can be used at a later point for correcting the measured time of arrival in each channel before calculating the speed of sound using the above-described equations.

The device and method according to the present invention can also utilize three transmitters and a single receiver. The transmitters can be positioned at a predetermined distance from one another, and as such, transmit different pulses entering the soft tissue 22 at different locations. These pulses would be received by the receiver at three different times. Accordingly, the computer 259 would be able to generate at least three equations (which are similar to the equations described above), to solve for three unknown variables (i.e., ϕ, the acoustic velocity V_B, and the distance h). Similarly, it is also possible to transmit these three pulses using a single transmitter, while each of the pulses would be received by a separate receiver (i.e., three receivers). These three receivers would also be positioned at a predetermined distance from one another. The equations discussed would then be attainable so that the above described unknown variable would be solvable.

In particular, Fig. 8E shows an exemplary illustration of such linear phasable multi-element grid element 287 in the probe 250. The grid element 287 consists of "N" elements, each capable of functioning as a transmitter and as a receiver. Accordingly, other transmitters and receivers are also preferably configured as grid elements. The "n" elements (e.g., of a selected transmitter) are actuated with a predetermined phase displacement of the pulse, which generates an appropriate phase and shape of the pulse to be analyzed by other assigned grid elements (of a selected receiver). Using the above-described grid elements, it is possible to relocate

a measuring zone on surface of the bone in a direction A.

Further embodiments according to the device and method of the present invention are illustrated in Figs. 8F and 8G. A width of the first and second transmitters 251, 252, and a width of the first and second receivers 253, 254 are selected based on the wavelength, and an angle of a pitch of the transmitters 251, 252 and/or receivers 253, 254 is determined with respect to the horizontal plane. Due to the pitch of the transmitters 251, 252 and/or receivers 253, 254, a region 276 is defined below the pitched transmitters 251, 252 and/or the pitched receivers 253, 254. This region 276 is defined as an acoustic chamber of the probe 250, which facilitates accurate parameter settings of the probe 250. The region 276 may be filled by a liquid (and maintained in place by a holding layer), by an elastic material (e.g., silicone rubbers, polyurethane rubbers, etc.) or by a relatively hard material (e.g., hard polyurethane such as U146A and a chain extender UL143 manufactured by Polymer Gvulot). The acoustic parameters of this region 276 (i.e., a speed of sound, acoustic impedance, acoustic absorption, etc.) can be utilized to accurately determine the parameter setting of the probe 250.

According to another embodiment of the present invention, the probe 250 includes a barrier element 265 (shown in Figs. 8F and 8G) which is preferably an acoustic attenuator. The barrier element 265 facilitates the probe 250 to perform an acoustic search between the first and second transmitters 251, 252 and the first and second receivers 253, 254. In particular, the barrier element 265 is capable of preventing the pulse from being transmitted along the acoustic grease (on the skin 20) from the first transmitter 251 and/or the second transmitter 252 to the first receiver 253 and/or the second receiver 254.

With the angle of pitch γ_1 of the transmitters 251, 252 and the receivers 253, 254 being relative to an extension of the skin 20 (shown in Fig. 8F), the probe 250 allows the velocity in along the surface of the bone 18 to be measured

when the Critical angle γ is between γ_1 and γ_2. In such a case, the pitch angle of the transmitters 251, 252 and/or of the receivers 253, 254 determines the minimum limit of the range of the Critical angles, and the maximum range of the velocities being measured.

Accordingly, the distances between the elements of the probe 250 (i.e., $A_{251\text{-}254}$, $A_{251\text{-}253}$, $A_{252\text{-}254}$ and $A_{252\text{-}253}$), which appear in the above-described equations, are determined according to the distances between internal (upper) points 281, 282, 283, 284 of the respective transmitters 251, 252 and the respective receivers 253, 254. As shown in Fig. 8G, when the elements are positioned at a larger pitch angle γ_1, the distances $A_{251\text{-}254}$, $A_{251\text{-}253}$, $A_{252\text{-}254}$, $A_{252\text{-}253}$ are determined according to the distances between the external (lower) points 291, 292, 293, 294 of the respective transmitters 251, 252 and the respective receivers 253, 254. As such, these distances are larger than the distances illustrated in Fig. 8F, and the maximum external overall dimensions of the probe are also larger than those shown in Fig. 8F.

The barrier 265 can also be used to delay the travel time of the pulse from the transmitters 251, 252 to the receivers 253, 254. With the barrier 265 positioned between the transmitters 251, 252 and the receivers 253, 254, the travel time of the pulse transmitted from the respective transmitter 251, 252 via the soft tissue 22, the surface of the bone 18, through the soft tissue 22 and received by the respective receiver 253, 254 is smaller than the travel time of the pulse transmitted by the respective transmitter 251, 252, around the barrier 265 and reach the respective receiver 253, 254. Thus, the pulse propagating via the surface of the bone 18 from the respective transmitter 251, 252 will reach the respective receiver 253, 254 before the pulse that travels above the skin 20 and around the barrier 265.

Fig. 8H illustrates a preferred embodiment according to the present invention. In particular, the probe 250 according to the preferred embodiment encloses acoustic barriers 300A-300E, electrical barriers 301A-301F, the

transmitters 251, 252, the receivers 253, 254 and insulated electrical connections 302A-302D. The barrier 300A is substantially the same as the barrier 265 shown in Fig. 8G. The electric shield 301A is positioned at an internal edge of the second transmitter 252 between the second transmitter 252 and the barrier 300A. The acoustic barrier 300B is positioned above the second transmitter 252 substantially near the electrical shield 301A. The insulated connection 302B is coupled to the second transmitter 252 for transmitting pulses and signals generated by the second driver 256b. Preferably, the acoustic barrier 300B can be positioned substantially between the insulated connection 302B and the electrical shield 301A. The acoustic barrier 300C is positioned between the first transmitter 251 and the second transmitter 252, and is enclosed by the electrical shield 301B. The insulated connection 302A is coupled to the first transmitter 251 for transmitting pulses and signals generated by the first driver 256a. The electrical shield 301C is provided on an external edge of the probe 250 and substantially at an external edge of the first transmitter 251. The insulated connection 302A is situated between the electrical shields 301B, 301C.

The electric shield 301D is positioned at an internal edge of the first receiver 253 between the first receiver 253 and the barrier 300A. The acoustic barrier 300D is positioned above the first receiver 253 substantially near the electrical shield 301D. The insulated connection 302C is coupled to the first receiver 253 for transmitting pulses and signals to the first signal processor 257a. Preferably, the acoustic barrier 300D can be positioned between the insulated connection 302C and the electrical shield 301D. The acoustic barrier 300E is positioned between the first receiver 253 and the second receiver 254, and is enclosed by the electrical shield 301E. The insulated connection 302D is coupled to the second receiver 254 for transmitting pulses and signals to the second signal processor 257b. The electrical shield 301F is provided on an external edge of the probe 250 (opposite to the edge situating the electrical shield 301C), and substantially at an

external edge of the second receiver 254. The insulated connection 302D is situated between the electrical shields 301E, 301F. Fig. 8I shows an elarged view of an exemplary transmitter and/or receiver as a piezoelement.

As shown in Fig. 8H, the propagation time of the pulse generated by the transmitter 251, 252, which travels above the skin 20 and around the acoustic shields 300A-300E, is delayed because the elements in the probe 250 are designed in a labyrinth type manner. In particular, the dimensions of the acoustic barriers 300A-300E and of the electrical shields 301A-301F are illustrated below in Table 1. As shown in Table 1, the dimensions and characteristics of the transmitters 251, 252 and the receivers 253, 254, and the distances therebetween, vary depending if the transmitter and/or the receiver are for a phalanx (bone in middle finger) analysis or for a radius(hand)/tibius(leg) analysis:

Table 1

Probe type	A1 mm	A2 mm	Temp °C	F MHZ	L mm	B1 mm	B2 mm	B3 mm	B4 mm	D1 mm	D2 mm	H1 mm	H2 mm	H m
Phalanx	8	2	23	1.25	23.5	3	11.5	15	18.5	0.5	1.3	15	0.5	1
radius/ tibia	10.5	4	23	1.25	40.5	4	20.3	26.1	31.9	0.5	1.75	15	0.5	1

In a further embodiment according to the present invention, a body of the probe 250 is separated from a holder (e.g., a probe holder) encasing the probe 250 with further barrier substantially similar composition as that of the barriers 265, 300A-300E. Thus, the pulse generated by the transmitter 251, 252 would not be able to escape through the probe holder and be received by receivers 253, 254 before the pulse is propagated through the soft tissue 22 and via the surface of the bone 18. This further barrier preferable has a high acoustic attenuation. As such, a gas-filled (e.g., air filled) gap can serve as the further barrier. In addition, the further barrier can also be composed of sponge materials, porous materials, etc.

Table 2 shows preferable compositions of the body of the probe 250, the acoustic chamber 276, the acoustic barrier 265, 300A-300E, and of the electrical shield 301A-301F, and an exemplary list of manufacturers (and the respective part numbers) for these elements:

Table 2

Element	Composition	Manufacture Number	Vendor
Body of Probe (250)	Polyurethane	U146-0A + chain extender UL 143	Polymer Gvulot, Israel
Acoustic Chamber (276)	Polyurethane	U146-0A + chain extender UL 143	Polymer Gvulot, Isreal
Acoustic Barrier (265, 300A-300E)	Neoprene (i.e., expanded rubber) or Polyurethane	CIG-3 2529/14A+ isocyanate 44V20	Regumi 1978 Ltd., Israel Polyurethane Ltd., Haifa,
Electrical Shield (301A-301F)	Copper Foil tape	8271-0050-39	Instrument Specialties, US

The devices shown in Figs. 8C-8I (and the method associated therewith) are particularly useful when the plane of the bone 18 is not parallel to the plane of the skin 20. In addition, these devices and methods can be utilized when the extension of the pulse transmitted by the first transmitter 251 is perpendicular to the plane of the bone 22 at a first location 285 where the pulse meets the surface of the bone 22, while the extension of the pulse transmitted by the second transmitter 252 is not perpendicular to the plane of the bone 22 at a second location 286 where the pulse meets the surface of the bone 22 (as shown in Fig. 8J). When locating a first surface S_1 at the first location 285 using the first transmitter 251, conventional devices and methods could not easily locate a second surface S_2 at the second location 286 using the second transmitter 252. Even by locating an intermediate position, the conventional devices and methods could not provide a precise calculation of the velocity of the pulse traveling at the surface of the bone 18. Fig. 8K shows another configuration of the varying planes of the bone 18, and the pulse propulsion by the first transmitter 251 to the

first surface S_1, and by the second transmitter 252 to the second surface S_2. As such, the amplitude of the pulse can be reduced.

The embodiments of the devices and methods according to the present invention (as shown in Figs. 8C-8K) provide information on the distance of the bone 18 from the transmitters 251, 252 and the receivers 253, 254, and thus providing the following advantages:

1. Reduces the difficulties of searching and locating of the bones having complex surface shapes, and simplifying and accelerating the bone scanning process; and

2. Reduces mistakes in measuring the ultrasound velocity due to the inconsistencies in the measured geometrical dimensions of the soft tissue 22, between the probe 250 and the surface of the bone 18.

Acoustic bone velocity measurement has many uses. A first use is finding fractures and strains in bones. When a bone is overstressed or fractured (even a hairline fracture which is hard to see in X-ray images), its acoustic velocity changes markedly at the locations surrounding the fracture. Owing to the high resolution of some embodiments of the present invention, fractures in the wrist bones can also be identified, wherein the prior art devices are not capable of such discrimination.

A second use is estimating the density of the bone and portions thereof to determine the loss of minerals in the bone due to diseases of the bone, osteoporosis or low-gravity environments. It should be noted that the velocity is dependent mainly on Young's Modulus, i.e., the lower the velocity, the weaker the bone.

A third use is to chart the healing process of a broken bone. The common practice today is to keep the damaged bone in a cast until a predetermined period of time has elapsed. However, some patients require a longer or shorter healing period. X-ray images do not usually show enough detail to evaluate the integrity of the bone. By measuring and charting changes in acoustic bone velocity, a physician can more

accurately estimate the state of bone repair. In a preferred embodiment, a small hole is drilled in the cast and the acoustic bone velocity is measured without removing the cast. In some patients it is advantageous to compare changes in acoustic bone velocities of opposing limbs.

Another use of the invention is measuring the thickness of the cortex of the bone. Fig. 9 shows bone 18 having an inner core 316 and a cortex 314. The general diameter of bone 18 is D and the diameter of inner core 316 is d. Thus, the thickness of cortex 314 is (D-d)/2.

In accordance with a further embodiment of the present invention, control unit 100 estimates the thickness of cortex 314 through utilization of an theoretically-derived and empirically-validated, non-dimensional curve of normalized velocity vs. normalized thickness, as shown in Fig. 10 to which reference is now made. A discussion of the creation of the curve in Fig. 10 is discussed in the book, Stress Waves in Solids, written by H. Kolsky, Oxford and Clarendon Press, 1953. Furthermore the probe 250 shown in Figs. 8C-8I can advantageously be used for these determinations.

The precise shape of the curve varies with the type of material being measured. However, it is has been determined by the present inventors that the shape of the curve is approximately constant for human bones.

The velocity V_L in the curve of Fig. 10 is normalized by the velocity V_o that would be achieved in an infinite solid and the thickness is normalized by the wavelength, λ, of the signal from the transmitter 70. λ is, of course, determined by V_{18}:

$$\lambda = V_{18}/f \qquad (41)$$

where f is the frequency of the ultrasound signal. It has been determined by the inventors that the curve is approximately the same whether the thickness is the thickness D (Fig. 9) of bone 18 or it the thickness (D - d)/2 (Fig. 9) of cortex 314. The proposed explanation is that the when the cortex is thick relative to λ, the inner portions of the bone

have no effect on the acoustic velocity. However, when the cortex is thin relative to λ, the inner portions of the bone affect the acoustic velocity. The inner portions of bones are usually much softer than the cortex, so their acoustic velocity is much lower than the cortex's acoustic velocity. Thus, if a higher frequency is used, a thinner bone can be measured.

It is noted that the curve has a region 330, for relatively small velocity ratios and small diameter/wavelength ratios and a region 332 for diameter/wavelength ratios greater than about 1.5 which is asymptotic to 1.0.

To estimate the thickness (D - d)/2 for a bone 18, transmitter 70 is operated twice, once with a high frequency input signal and once with a low frequency input signal. For each measurement, control unit 100 operates, as described hereinabove with respect to Figs. 4A and 4B, to determine the received velocity. Alternatively, in a preferred embodiment of the present invention transmitter 70 is a broadband transmitter and is operated only once. In addition, control unit 100 comprises frequency filters for separating received high frequency signals from low frequency signals. Thus, the high frequency velocity and the low frequency velocity are simultaneously measured.

The response to the high frequency input signal, which has a low wavelength λ, provides a velocity data point 334 somewhere along the region 332 from which the velocity V_o can be determined. The precise location of data point 334 is unknown, since the thickness is not yet determined. However, it is unimportant.

The response to the low frequency input signal provides a velocity data point 336 somewhere within the region 330. Because the velocity V_L is known from the measurement and the velocity V_o is known from the previous measurement, the location on the curve of the data point 336 is known. Therefore, the ratio (D - d)/(2*λ) can be determined. Since λ is known from the frequency of the transmitter 70 and the known velocities, the thickness of cortex 314 (D - d)/2 can be

determined.

It should be appreciated that the above described fourth use is more practical when using the instant method of acoustic bone velocity determination, than when using prior art methods. High frequency signals attenuate rapidly when traveling through bone material. So, only when the path in bone 18 is short, as is possible using the present invention, are high frequency ultrasonic waves practical. Thus, in a preferred embodiment of the invention, the high frequency input signal used is higher than in the prior art and therefore, suitable for thinner bones.

It should be noted that the above described method of emitting a single broadband signal instead of two frequency specific signals is applicable to prior art methods of bone o thickness determination, such as the methods shown in U.S. patent No. 5,143,072.

Reference is now made to Figs. 11 and 12 which illustrate aspects of a further embodiment useful for scanning across a section 448 of a human body, such as an arm.

In this embodiment, a sensor device formed of an array of ultrasonic transmitter/receiver cells 450 is placed onto or wrapped around section 448 or is formed into a sock-like element 460. The cells of array 450 are preferably formed from a piezoelectric material, such as a piezoceramic. Array 450 is typically acoustically coupled to section 448 in a standard manner.

Typically, as shown in Fig. 12, the input and output wires of each cell of array 450 are connected to an analog matrix multiplexer 451 which, in turn, is connected to a driver 452 and to a signal processing unit 454. Driver 452 and unit 454 are typically controlled via a microprocessor 455.

Multiplexer 451 enables each cell of array 450 to be individually accessed and is operative to define each cell as a receiver, a transmitter, a transmitter-receiver or as non-active.

The cells of array 450 may be individually too small to

form ultrasonic transducers for use in prior art methods, due to the attenuation caused by long paths through bone 18. Therefore, a plurality of groups of cells of array 450 in desired locations were electronically and selectably defined to be the ultrasonic elements. In a preferred embodiment of the present invention, each cell of array 450 is a separate ultrasonic element as described herein. Alternatively, groups of cells are defined as transducers, as shown in the prior art. However, one of the operation modes described below is preferably used.

A first preferred method of operation is to select cells and groups of cells that approximate the functionality of the embodiments described hereinabove. Thus, optimal placement of transmitter/receivers can be achieved without moving ultrasonic elements.

In a preferred embodiment of the invention, a two step method is used to determine the configuration of array 450 as transmitters and receivers. As described hereinabove, a preferred embodiment of the invention uses sensors which are optimized for a specific soft tissue thickness between the sensor and bone 18. Using array 450 to image bone 18 it is possible to determine the thickness of underlying soft tissue 22, before bone velocity determination:

(a) determining the thickness of underlying soft tissue 22; and

(b) configuring array 450 into transmitters, receivers and transmitter/receivers having optimal distances therebetween, which are calculated based on the determined thickness of soft tissue 22.

Alternatively, an ultrasonic sensor comprises one or more transmitters and/or receiver and a cell array. The cell array is configured to be used in place of some, but not all of the ultrasonic elements described in the embodiments hereinabove. For example, in the embodiment of Fig. 5A, transmitter/receivers 82 and 84 can be emulated by a cell array.

A second preferred method of operation maps bones and

soft tissues by operating different cells of array 450 instead of moving a unit comprising a plurality of ultrasonic units. Thus, the bone velocity at different positions and in different directions can be measured without physically moving the apparatus.

It should be noted that many prior art methods of bone acoustic velocity determination use an inexact estimate for the values of soft tissue thickness and soft tissue velocity. If an embodiment of the present invention is used to determine more accurate values for the soft tissue thickness and velocity, these prior art methods will give more precise results.

In addition, measurement of soft tissue velocity is useful for determination of water, fat and muscle content of the tissue. Thus, dehydration and rehydration of a patient can be analyzed by measuring the soft tissue velocity, in a selected part of the patient's body, over a period of time. The muscle/fat ratio of the tissue can be determined if the water content of the tissue is known, or by averaging several results taken before and after the patient drinks water.

When scanning a human female, breast, the air tissue boundary can be used as a reflection plane. Preferably the breast is urged against a resilient form so that it does not move during imaging.

In a further embodiment of the present invention, scanning is accomplished using a cell array as described hereinabove. Preferably, the scans include scans of the same soft tissue from multiple directions so that a velocity image of the tissue can be reconstructed, preferably using tomographic methods.

Figs. 13A and 13B show yet another embodiment of the invention related to soft tissue imaging. Fig. 13A shows a general soft tissue portion 508 which contains a soft tissue portion 506 which has a substantially different acoustic velocity. An example of such tissues is a human breast and a pathological neoplasm, such as a malignant tumor. The sensor

used preferably comprises an array, of which a plurality of cells 502 comprise a scanner, as known in the art of ultrasound imaging. At least one cell comprises a transmitter 500 and at least one cell comprises a receiver 504. Scanner 502 scans tissue 508 until the location of tissue 506 is found (a scanning beam is shown by two parallel fines). Alternatively, tissue 506 is invisible using standard ultrasound imaging. In this case, the position of tissue 506 is preferably determined beforehand using another imaging method which also determines landmarks. These landmarks are found by scanner 502 and the position of tissue 506 is ascertained. The soft tissue velocity of tissue 508, in areas surrounding tissue 506 is determined using transmitter 500, receiver 504 and the plurality of cells which comprise scanner 502, using determination methods as described hereinabove. Then, the soft tissue velocity is determined in a manner which will force the path of the measurement wave to path through tissue 506. For example, if a cell grid is used, a plurality of soft tissue measurements are acquired and the measurements which are substantially different as assumed to have traveled through tissue 506.

Fig. 13B in conjunction with Fig. 13A shows a method of increasing the contrast between the measurement of the velocity in tissue 508 and the measurement of the velocity in tissue 506. The travel time in segments Aa, bB, Bd, Bb', Dd' and a'A' are constant and unaffected by the presence of tissue 506. These travel times can be determined beforehand in regions which do not include tissue 506. As a result, the tissue velocity in tissue 506 can be better determined using only the segments ab, dd' and b'a'. Alternatively or additionally, knowledge of the approximate depth of tissue 506 can be used to increase the contrast in a similar manner.

Apparatus for soft tissue imaging can comprise as few as two transmitter/receivers, as described hereinabove with reference to soft tissue velocity determination methods. However, such apparatus preferably comprises a plurality of ultrasonic elements, preferably an array, such as array 450

(shown in Fig. 11). Alternatively, apparatus, as described hereinabove with reference to bone acoustic velocity determination, can also be used for soft tissue velocity determination. Typically in such cases, the bone traveling wave is either not transmitted, not received or not analyzed.

A single measurement in some preferred embodiments of the invention is only 2.5 milliseconds long, which is faster than most body rhythms. Several measurements taken along the course of a body rhythm can be used to measure the effect of the body rhythm on the measurement.

The above described embodiments are described in relation to a bone with surrounding soft tissue. However, a person skilled in the art will appreciate that these selfsame embodiments are just as useful for determining the mechanical properties of a general structure which is surrounded by layered material having a lower acoustic velocity. For example, metal braces which are encased in rubber.

As described hereinabove the acoustic velocities in a two layer structure are determined. It should be appreciated that the acoustic velocities in a multi-layer structure can be determined, providing that the layers are in a ascending order of acoustic velocity. For example, if a fast layer is covered with a slow layer and further covered with a very slow layer, the acoustic velocity of the very slow layer is first determined, then of the slow layer and then of the fast layer. Each determined velocity is used for determining the velocities in the next layer. However, if the slow layer and the fast layer are transposed, the slow layer is masked by the fast layer and the acoustic velocity of the slow layer cannot be determined.

Fig. 14 shows an embodiment of the invention as used in conjunction with a scanning type ultrasonic sensor. A typical scanning ultrasonic sensor uses an array of cells, such the array 450 described above, to form a scanning beam, which scans a body portion, such as bone 18 and soft tissue 22. In a preferred embodiment of the present invention, the acoustic velocity of bone 18 is determined concurrently with the

scanning of the bone 18. Thus, an image of the bone 18 is acquired together with a map of the bone acoustic velocity, or bone strength, in the same area. The plurality of cells 456 form a scanning transmitter and a plurality of cells 458 form a receiver for imaging bone 18. The acoustic bone velocity is preferably determined between the scanning pulses.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein.

What Is Claimed Is:

1. A method for analyzing a solid material by propagating an acoustic wave via a surface of the solid material at a first acoustic velocity, the acoustic wave passing through an interposing medium with a second acoustic velocity, the method comprising the steps of:

transmitting a first ultrasonic wave along a first transmission path from a first transmitting location, the first transmission path extending through the interposing medium, via a surface of the solid material, and through the interposing medium to reach a first receiving location, the first transmitting location positioned at a first distance from the first receiving position;

measuring a first travel time of the first ultrasonic wave along the first transmission path;

transmitting a second ultrasonic wave along a second transmission path from a second transmitting location, the second transmission path extending through the interposing medium, via the surface of the solid material, and through the interposing medium to reach a second receiving location, the second transmitting location positioned at a second distance from the second receiving position;

measuring a second travel time of the second ultrasonic wave along the second transmission path;

transmitting a third ultrasonic wave along a third transmission path from a third transmission location being the first transmission location, the second transmitting location or a further transmission location, the third transmission path extending through the interposing medium, via the surface of the solid material, and through the interposing medium to reach a third receiving location being the first receiving location, the second receiving location or a further receiving location, the third transmitting location positioned at a third distance from the third receiving position;

measuring a third travel time of the third ultrasonic wave along the third transmission path; and

calculating the first acoustic velocity as a function of the first distance, the second distance, the third distance, the first time, the second time, the third time and the second acoustic velocity.

2. The method according to claim 1, further comprising the step of:

measuring a thickness of the interposing medium, wherein the first acoustic velocity is determined as a further function of the thickness.

3. The method according to claims 1 or 2, wherein the third transmission location is the first transmission location or the second transmitting location, and wherein third receiving location is the first receiving location or the second receiving location.

4. The method according to claims 1 or 2, wherein the third transmission location is the first transmission location, and wherein third receiving location is the second receiving location.

5. The method according to claims 1 or 2, wherein the third transmission location is the second transmitting location, and wherein third receiving location is the first receiving location.

6. The method according to claims 1-5, further comprising the steps of:

transmitting a fourth ultrasonic wave along a fourth transmission path from a fourth transmission location being another one of the first transmission location, the second transmitting location or the further transmission location, the fourth transmission path extending through the interposing medium, via the surface of the solid material, and through the interposing medium to reach a fourth receiving location being another one of the first receiving location, the second

receiving location or the further receiving location, the fourth transmitting location positioned at a fourth distance from the fourth receiving position;

measuring a fourth travel time of the fourth ultrasonic wave along the fourth transmission path; and

before the step of calculating the first acoustic velocity, calculating the second acoustic velocity as a function of the first distance, the second distance, the third distance, the fourth distance, the first time, the second time, the third time and the fourth time.

7. The method according to claims 1-6, wherein the transmission locations and the receiving locations extend along a first axis, wherein the surface of the solid material extends along a second axis at a first angle from the first axis.

8. The method according to claims 1-7, further comprising the step of:

calculating a midpoint between one of the first and second transmission locations and one of the first and second receiving locations, wherein the thickness being a shortest distance between the midpoint and the surface of the solid material, and wherein the first acoustic velocity is calculated as a further function of the midpoint.

9. The method according to claims 1 or 2, wherein:

the transmission locations and the receiving locations are situated along a first axis, and

the surface of the solid material extends along a second axis at a first angle from the first axis.

10. The method according to claim 9, wherein the first acoustic velocity is calculated as a further function of the first angle.

11. The method according to any of claims 1-10, wherein the

interposing medium includes living tissue.

12. The method according to any of claims 1-11, wherein the solid material includes an in vivo bone.

13. The method according to any of claims 1-11, wherein the solid material is denser than the interposing medium.

14. The method according to claims 1-13, wherein:

the first ultrasonic wave is transmitted by a first transmitter and received by a first receiver,

the second ultrasonic wave is transmitted by a second transmitter and received by a second receiver, and

the third ultrasonic wave is transmitted by first transmitter, the second transmitter or a further transmitter, and received by the first receiver, the second receiver or a further receiver.

15. The method according to claims 6-13, wherein:

the first ultrasonic wave is transmitted by a first transmitter and received by a first receiver,

the second ultrasonic wave is transmitted by a second transmitter and received by a second receiver,

the third ultrasonic wave is transmitted by the first transmitter, the second transmitter or a further transmitter, and received by the first receiver, the second receiver or a further receiver, and

the fourth ultrasonic wave is transmitted by another one of the first transmitter, the second transmitter or the further transmitter, and received by another one of the first receiver, the second receiver or the further receiver.

16. The method according to claims 1-15, wherein the first, second and third travel times are measured simultaneously.

17. The method according to claims 6-16, wherein the first,

second, third and fourth travel times are measured simultaneously.

18. A device for determining an acoustic velocity of a solid material through an interposing medium, comprising:

an first ultrasonic transmitter transmitting a first wave along a first path, the first path extending into the interposing medium towards a surface of the solid material, the first wave traveling via the surface of the solid material and to re-enter the interposing medium;

a second ultrasonic transmitter transmitting a second wave along a second path, the second path extending into the interposing medium towards the surface of the solid material, the second wave traveling via the surface of the solid material and to re-enter the interposing medium;

a first ultrasonic receiver receiving the first wave and positioned at a first distance from the first ultrasonic transmitter;

a second ultrasonic receiver receiving the second wave and positioned at a second distance from the second ultrasonic transmitter,

wherein the first ultrasonic transmitter, the second ultrasonic transmitter or a further ultrasonic transmitter transmits a third wave along a third path, the third path extending into the interposing medium towards the surface of the solid material, the third wave propagating via the surface of the solid material to re-enter the interposing medium, and

wherein the first ultrasonic receiver, the second ultrasonic receiver or a further ultrasonic receiver receives the third wave, the transmitting ultrasonic transmitter being positioned at a third distance from the receiving ultrasonic receiver; and

a control unit controlling at least one of the first, second and further ultrasonic transmitters to transmit the first, second and third waves, the control unit measuring a first travel time of the first wave along the first path, a

second travel time of the second wave along the second path, and a third travel time of the third wave along the third path,

wherein the control unit determines the acoustic velocity of the solid material as a function of the first distance, the second distance, the third distance, the first travel time, the second travel time and the third travel time.

19. The device according to claim 18, wherein the transmitting ultrasonic transmitter includes the first ultrasonic transmitter or the second ultrasonic transmitter.

20. The device according to claims 18 or 19, wherein the receiving ultrasonic receiver includes the first ultrasonic receiver or the second ultrasonic receiver.

21. The device according to claims 18-20, wherein the transmitting ultrasonic transmitter includes the first ultrasonic transmitter, and wherein the receiving ultrasonic receiver includes the second ultrasonic receiver.

22. The device according to claims 18-20, wherein the transmitting ultrasonic transmitter includes the second ultrasonic transmitter, and wherein the receiving ultrasonic receiver includes the first ultrasonic receiver.

23. The device according to claim 18-22, wherein the interposing medium has a further acoustic velocity, and wherein the control unit determines the acoustic velocity of the solid material as a further function of the further acoustic velocity.

24. The device according to claim 18,

wherein a particular transmitter being another one of the first ultrasonic transmitter, the second ultrasonic transmitter or the further ultrasonic transmitter transmits a fourth wave along a fourth path, the fourth path extending

into the interposing medium towards the surface of the solid material, the fourth wave propagating via the surface of the solid material and to re-enter the interposing medium, and

wherein a particular receiver being another one of the first ultrasonic receiver, the second ultrasonic receiver or the further ultrasonic receiver receives the fourth wave, the particular transmitter positioned at a fourth distance from the particular receiver.

25. The device according to claim 24, wherein the interposing medium has a further acoustic velocity, and wherein the control unit measures a fourth travel time of the fourth wave along the fourth path and determines the further acoustic velocity as a function of the first distance, the second distance, the third distance, the fourth distance, the first travel time, the second travel time, the third travel time and the fourth travel time.

26. The device according to claims 23, wherein the particular transmitter includes the first ultrasonic transmitter, and wherein the particular receiver includes the second ultrasonic receiver.

27. The device according to claims 24, wherein the particular transmitter includes the second ultrasonic transmitter, and wherein the particular receiver includes the first ultrasonic receiver.

27. The device according to claims 18-27, wherein the ultrasonic transmitters and receivers are situated along a first axis, wherein the surface of the solid material extends along a second axis at a first angle from the first axis.

28. The device according to claims 18-28, wherein the control unit determines a thickness of the interposing medium, and wherein the acoustic velocity is determined as a further function of the thickness.

29. The device according to claims 28, wherein the control unit determines a midpoint between one of the first and second ultrasonic transmitters and one of the first and second receivers, the thickness being a shortest distance between the midpoint and the surface of the solid material, and wherein the acoustic velocity is determined as a further function of the midpoint.

30. The device according to claim 28, wherein the acoustic velocity of the solid material is determined as a further function of the first angle.

31. The device according to claim 29, wherein the acoustic velocity of the solid material is determined as a further function of the first angle.

32. The device according to claims 18-31, wherein the interposing medium includes living tissue.

33. The device according to claims 18-32, wherein the solid material includes an in vivo bone.

34. The device according to claims 18-32, wherein the solid material is denser than the interposing medium.

35. The device according to claim 18-34, wherein the first, second and third travel times are measured simultaneously.

36. The device according to claim 25, wherein the first, second, third and fourth travel times are measured simultaneously.

37. The device according to claim 18-36, wherein the first and second transmitter are pitched at a second angle with respect to the first axis, and wherein the first and second ultrasonic receivers are pitched at a third angle with respect to the first axis, the second and third angles being

substantially equal.

38. The device according to claim 18-37,

wherein the first and second ultrasonic transmitters, and the first and second ultrasonic receivers are arranged in a grid of piezoelectric cells, and

wherein the control unit selectively activates at least one of the cells and measures the first, second and third travel time of the respective first, second and third waves.

39. The device according to claim 38, wherein the control unit coupled to a computer, the computer storing the first travel time, the second travel time, the third travel time, the first distance, the second distance, the third distance and the acoustic velocity of the solid material for further processing.

40. A method for analyzing a solid material by propagating an acoustic wave via a surface of the solid material at a first acoustic velocity, the acoustic wave passing through an interposing medium with a second acoustic velocity, the method comprising the steps of:

transmitting a first ultrasonic wave along a first transmission path, the first transmission path extending through the interposing medium and along a surface of the solid material;

measuring a first travel time of the first ultrasonic wave along the first transmission path;

transmitting a second ultrasonic wave along a second transmission path, the second transmission path extending through the interposing medium and along the surface of the solid material;

measuring a second travel time of the second ultrasonic wave along the second transmission path;

transmitting a third ultrasonic wave along a third transmission path from a third transmission location, the third transmission path extending through the interposing

medium and along the surface of the solid material;

measuring a third travel time of the third ultrasonic wave along the third transmission path; and

calculating the first acoustic velocity as a function of the first time, the second time, the third time and the second acoustic velocity.

41. The method according to claim 40, further comprising the steps of:

transmitting a fourth ultrasonic wave along a fourth transmission path, the fourth transmission path extending through the interposing medium and along the surface of the solid material;

measuring a fourth travel time of the fourth ultrasonic wave along the fourth transmission path; and

before the step of calculating the first acoustic velocity, calculating the second acoustic velocity as a function of the first time, the second time, the third time and the fourth time.

42. A method for determining a position of a solid material by propagating an acoustic wave via a surface of the solid material at a first acoustic velocity, the acoustic wave passing through an interposing medium with a second acoustic velocity, the method comprising the steps of:

transmitting a first ultrasonic wave along a first transmission path, the first transmission path extending through the interposing medium and along a surface of the solid material;

measuring a first travel time of the first ultrasonic wave along the first transmission path;

transmitting a second ultrasonic wave along a second transmission path, the second transmission path extending through the interposing medium and along the surface of the solid material;

measuring a second travel time of the second ultrasonic wave along the second transmission path;

transmitting a third ultrasonic wave along a third transmission path from a third transmission location, the third transmission path extending through the interposing medium and along the surface of the solid material;

measuring a third travel time of the third ultrasonic wave along the third transmission path; and

calculating an angle between a first axis extending along the surface of the bone and a second axis along which the first, second and third ultrasonic waves are transmitted, the angle being determined as a function of the first time, the second time, the third time, the first velocity and the second acoustic velocity.

43. The method according to claim 42, further comprising the steps of:

transmitting a fourth ultrasonic wave along a fourth transmission path, the fourth transmission path extending through the interposing medium and along the surface of the solid material;

measuring a fourth travel time of the fourth ultrasonic wave along the fourth transmission path; and

before the step of calculating the angle, calculating the second acoustic velocity as a function of the first time, the second time, the third time and the fourth time.

44. A method for determining a distance of a solid material from a transmission surface by propagating an acoustic wave via a surface of the solid material at a first acoustic velocity, the acoustic wave passing through an interposing medium with a second acoustic velocity, the method comprising the steps of:

transmitting a first ultrasonic wave along a first transmission path, the first transmission path extending through the interposing medium and along a surface of the solid material;

measuring a first travel time of the first ultrasonic wave along the first transmission path;

transmitting a second ultrasonic wave along a second transmission path, the second transmission path extending through the interposing medium and along the surface of the solid material;

measuring a second travel time of the second ultrasonic wave along the second transmission path;

transmitting a third ultrasonic wave along a third transmission path from a third transmission location, the third transmission path extending through the interposing medium and along the surface of the solid material;

measuring a third travel time of the third ultrasonic wave along the third transmission path; and

calculating the distance as a function of the first time, the second time, the third time, the first velocity and the second acoustic velocity.

45. The method according to claim 44, further comprising the steps of:

transmitting a fourth ultrasonic wave along a fourth transmission path, the fourth transmission path extending through the interposing medium and along the surface of the solid material;

measuring a fourth travel time of the fourth ultrasonic wave along the fourth transmission path; and

before the step of calculating the distance, calculating the second acoustic velocity as a function of the first time, the second time, the third time and the fourth time.

46. A method for analyzing a solid material by propagating an acoustic wave via a surface of the solid material at a first acoustic velocity, the acoustic wave passing through an interposing medium with a second acoustic velocity, the method comprising the steps of:

transmitting a first ultrasonic wave along a first transmission path, the first transmission path extending through the interposing medium and along a surface of the solid material;

measuring a first travel time of the first ultrasonic wave along the first transmission path;

transmitting a second ultrasonic wave along a second transmission path, the second transmission path extending through the interposing medium and along the surface of the solid material;

measuring a second travel time of the second ultrasonic wave along the second transmission path;

transmitting a third ultrasonic wave along a third transmission path from a third transmission location, the third transmission path extending through the interposing medium and along the surface of the solid material;

measuring a third travel time of the third ultrasonic wave along the third transmission path; and

calculating the first acoustic velocity as a function of the first time, the second time, the third time and the second acoustic velocity, wherein the first, second and third transmission paths at least partially overlap one another along the surface of the solid material.

47. The device according to claim 18, wherein the first distance, the second distance and the third distance are stored in Read Only storage device.

ABSTRACT OF THE DISCLOSURE

A device and method in which at least one transmitter and at least one receiver are situated on a skin of a patient. A first ultrasonic wave is transmitted along a first transmission path. The first transmission path extends through the interposing medium and along a surface of the solid material. The first travel time of the first ultrasonic wave along the first transmission path is thus measured. A second ultrasonic wave is transmitted along a second transmission path. The second transmission path also extends through the interposing medium and along the surface of the solid material. A second travel time of the second ultrasonic wave along the second transmission path is also measured. Then, a third ultrasonic wave is transmitted along a third transmission path. The third transmission path extends similarly to that of the first and second transmission paths. Thus, a third travel time of the third ultrasonic wave along the third transmission path is measured. Thereafter, a control device determines either the acoustic velocity via the surface of the solid material, an angle of the transmitter and the receiver with respect to the solid material or the distance from the solid material to the skin as a function of the distances between the at least one transmitter and the at least one receiver, and the first, second and third times.

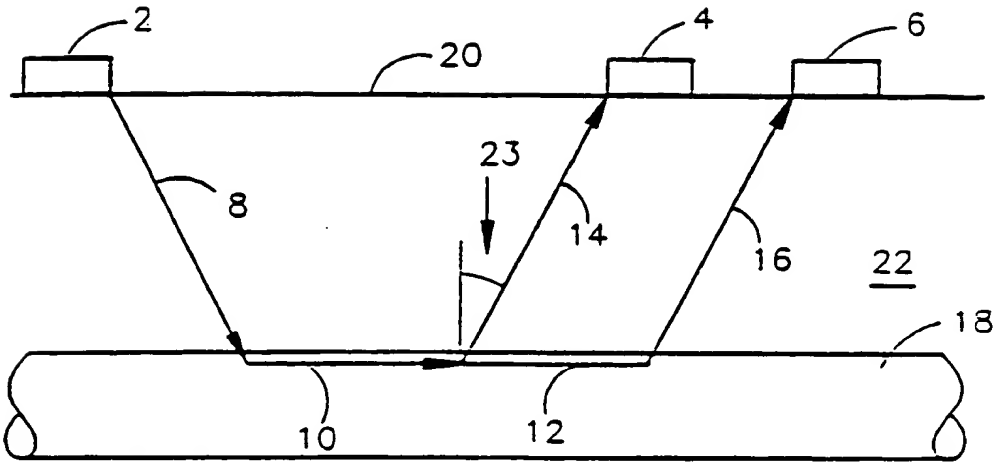


FIG. 1A PRIOR ART

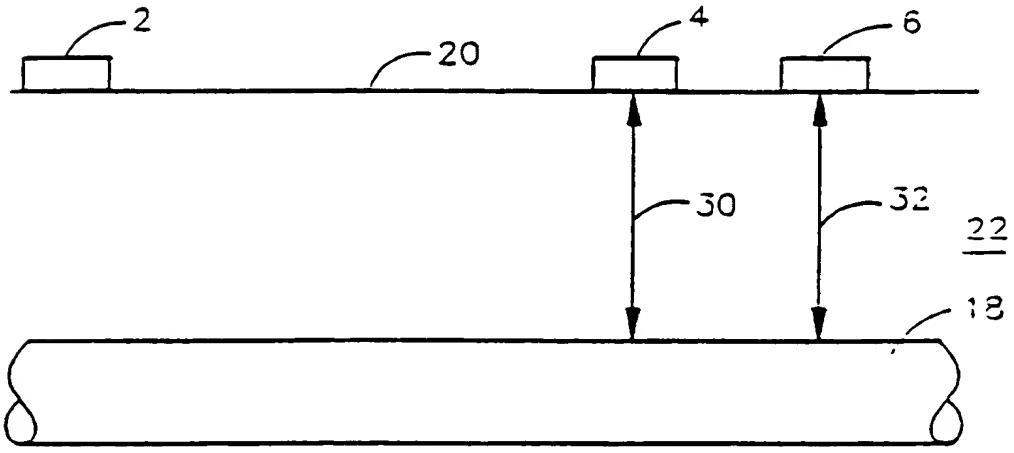
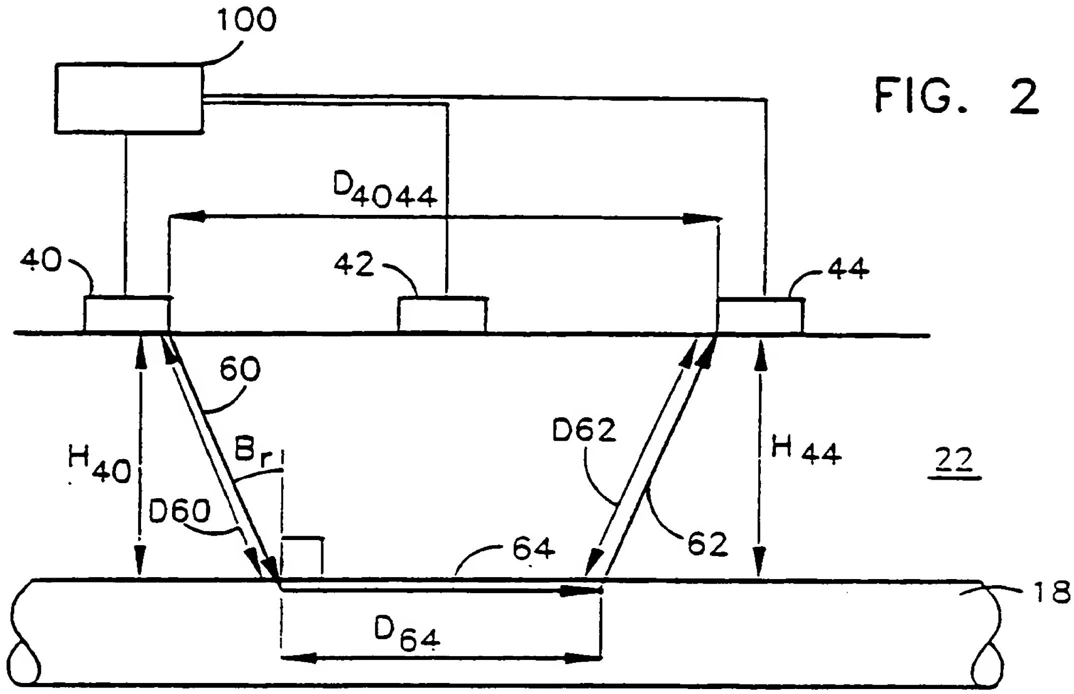


FIG. 1B PRIOR ART

FIG. 2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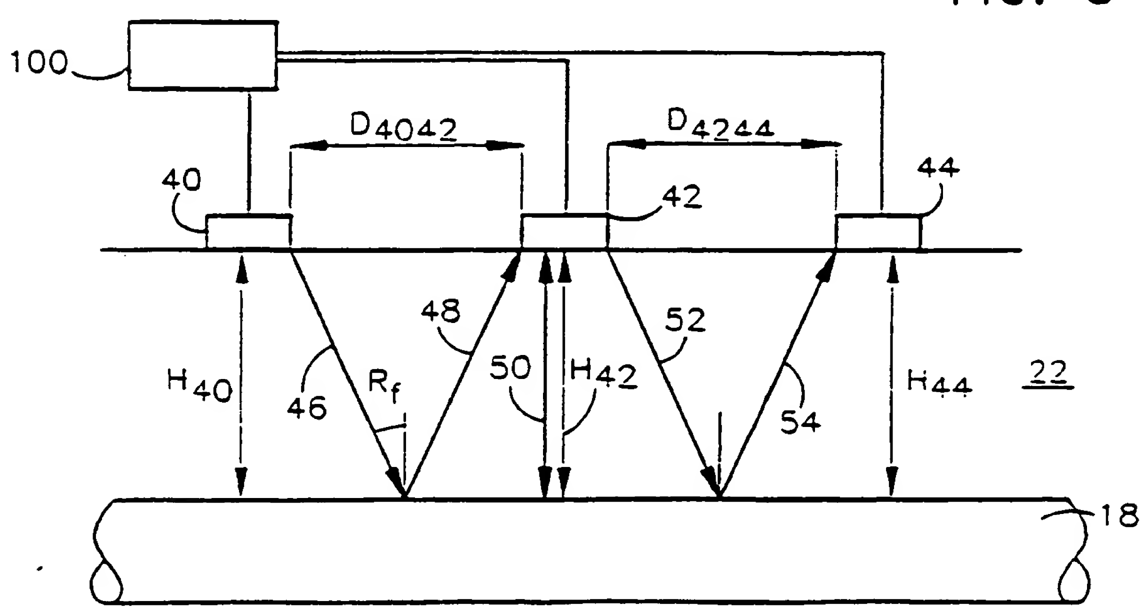
D64

FIG. 3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H44
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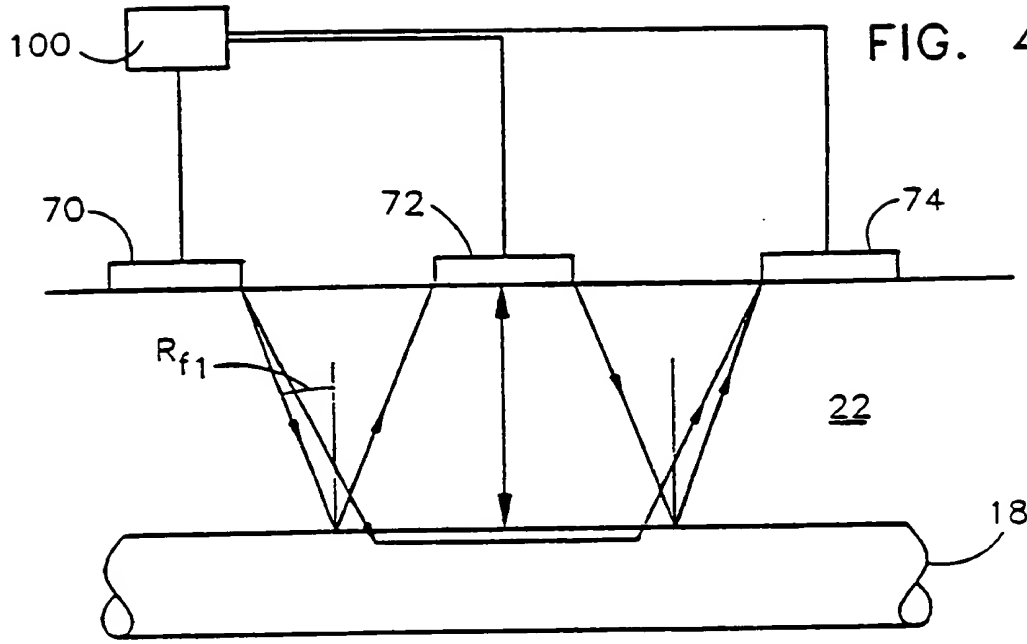


FIG. 4A

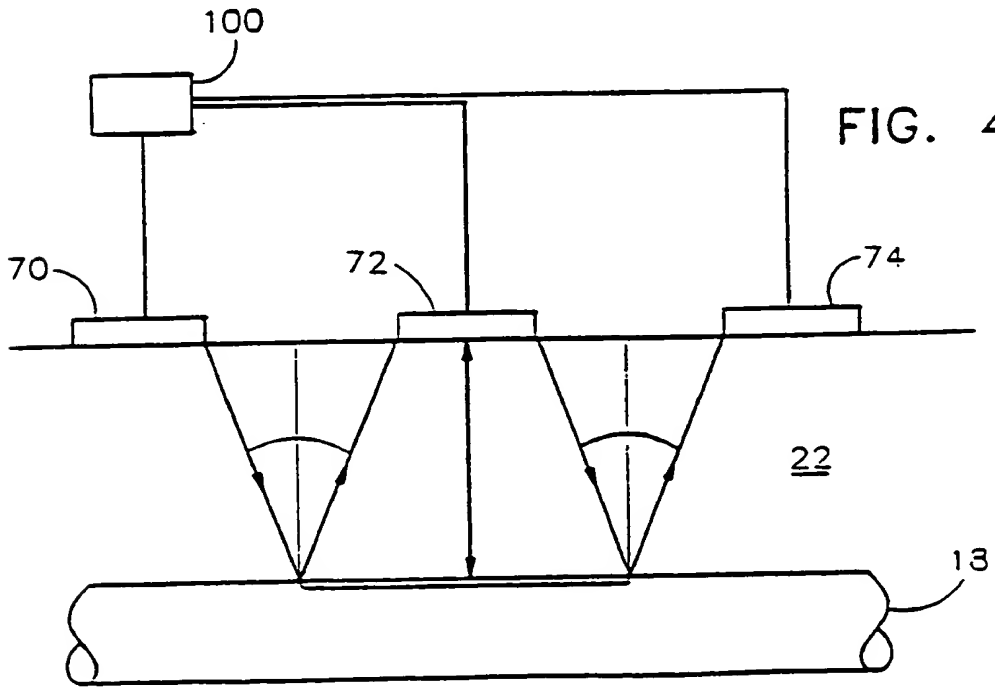
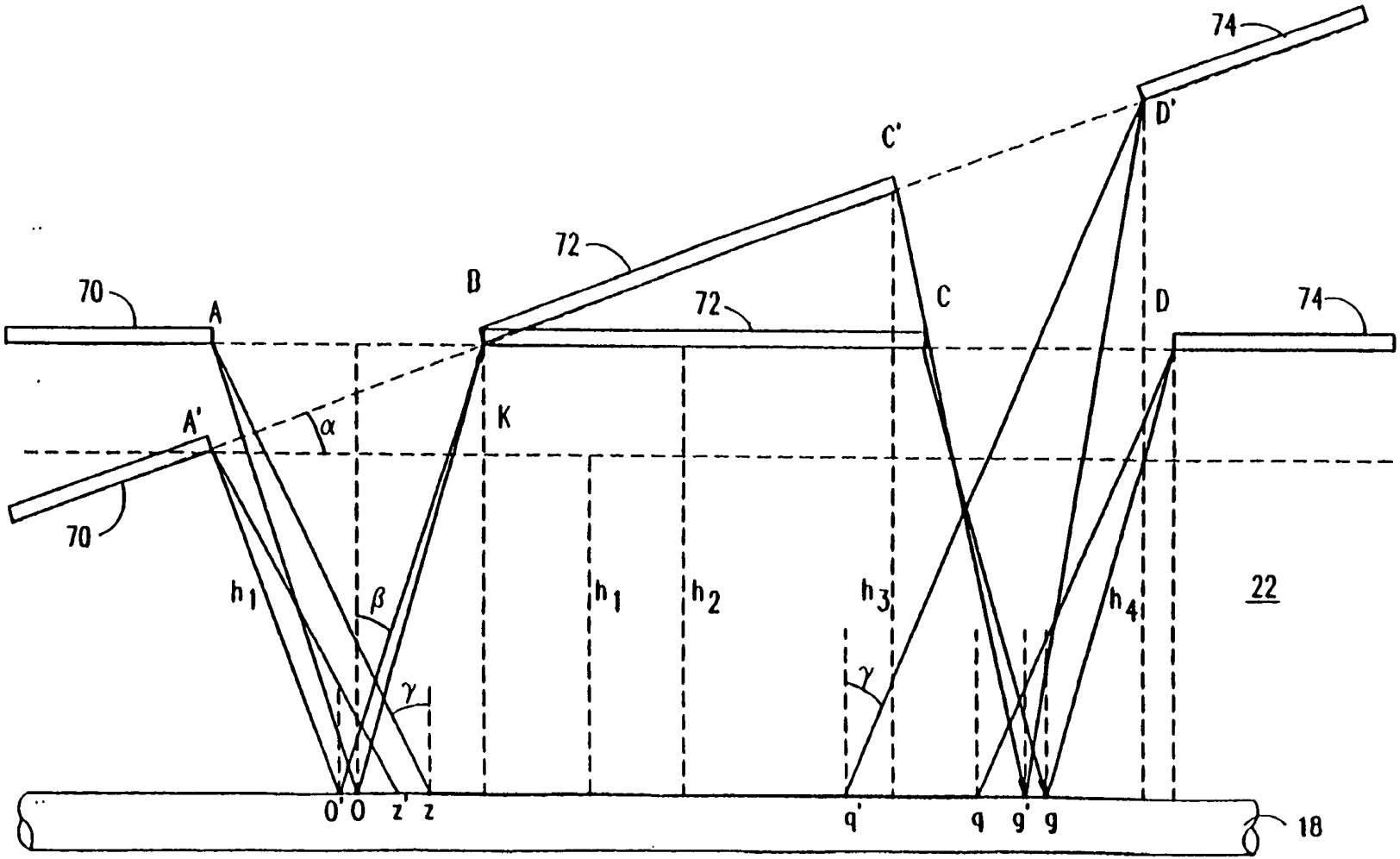


FIG. 4B

Fig 4C



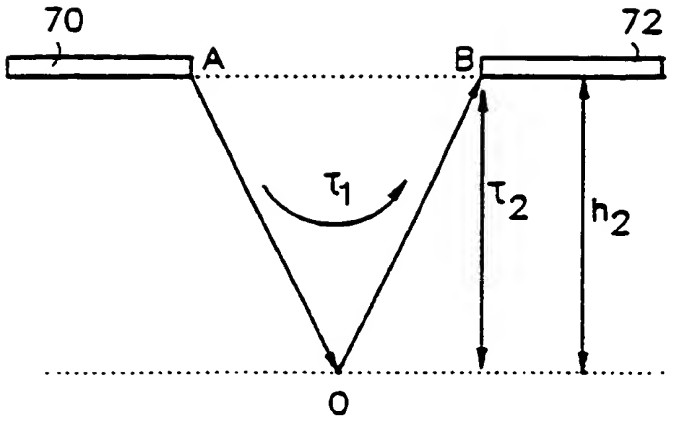


FIG. 4D

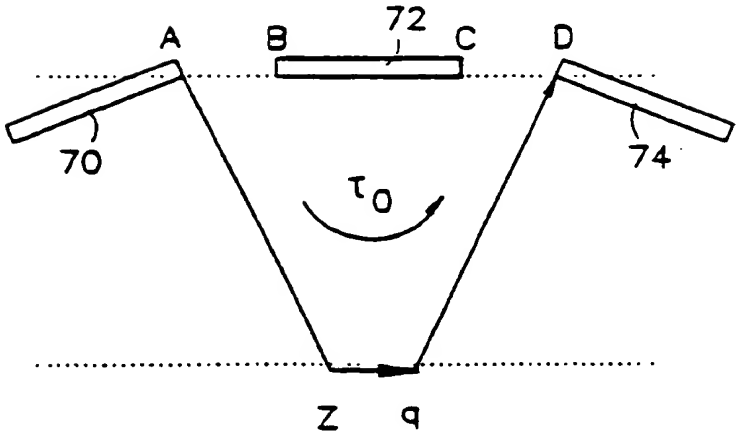


FIG. 4E

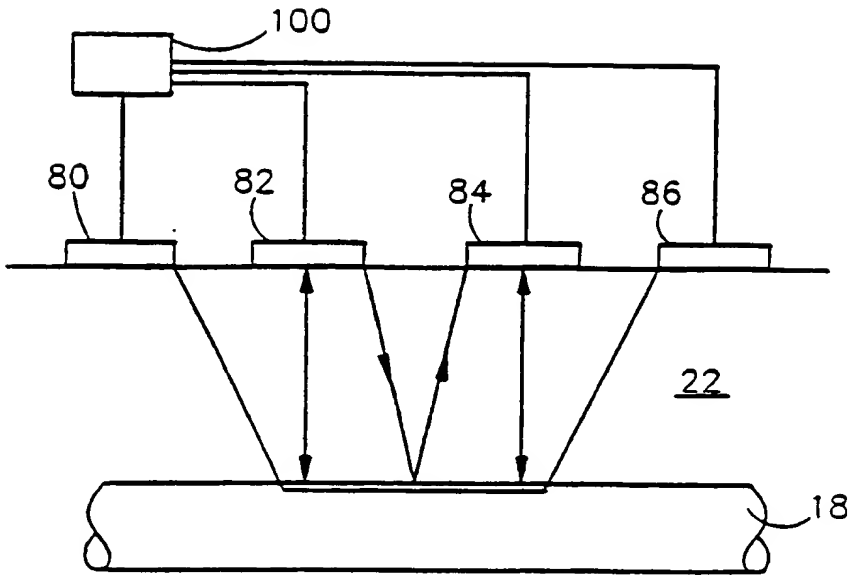


FIG. 5A

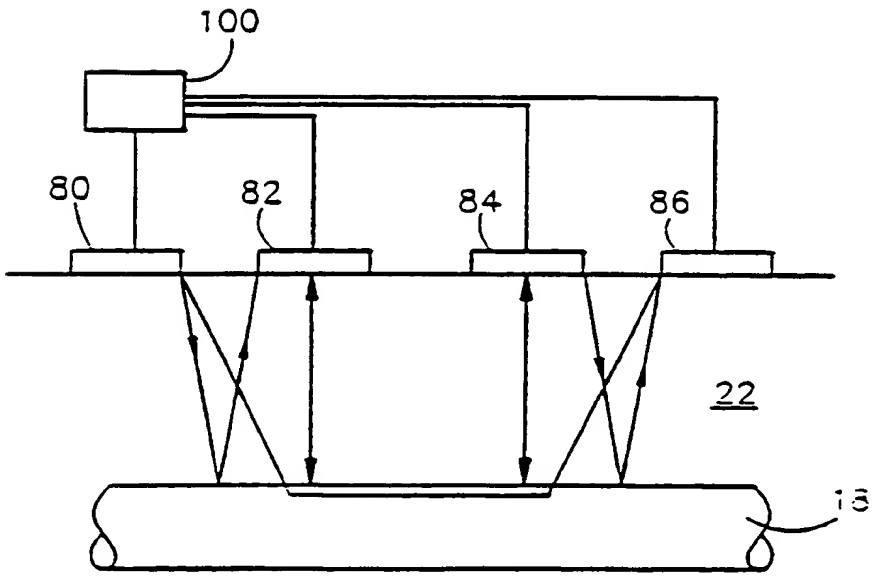


FIG. 5B

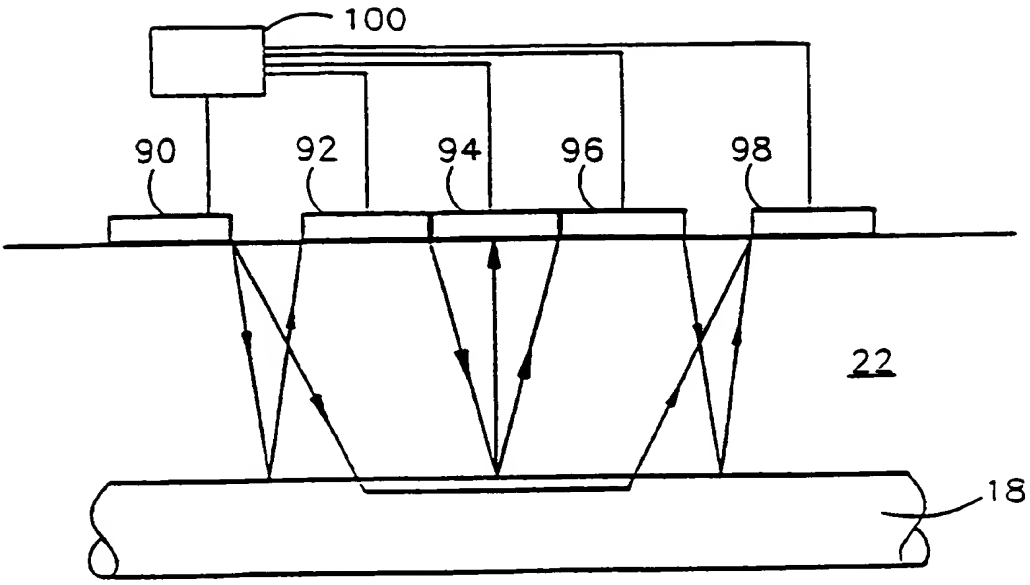


FIG. 6A

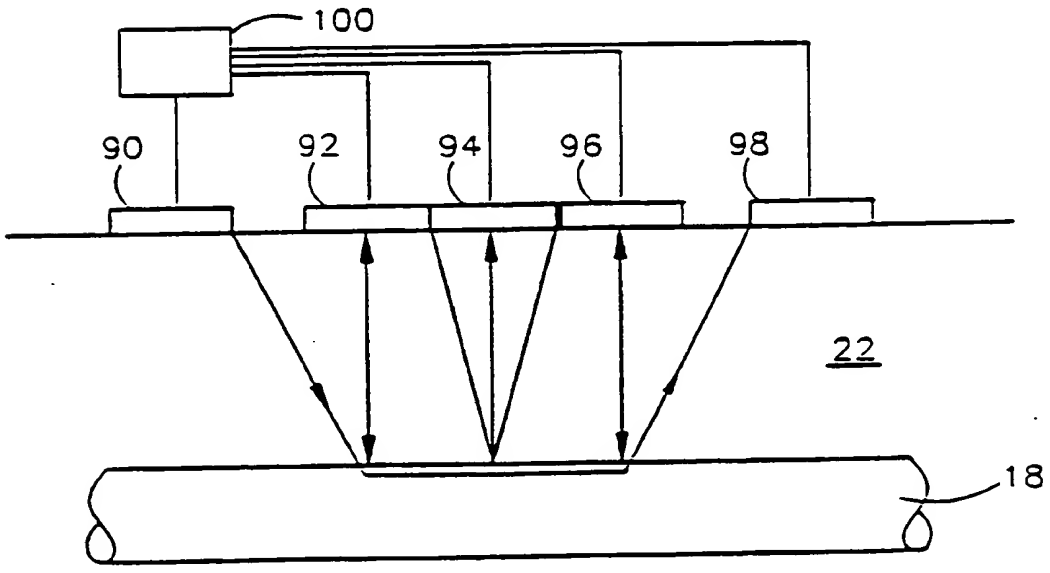


FIG. 6B

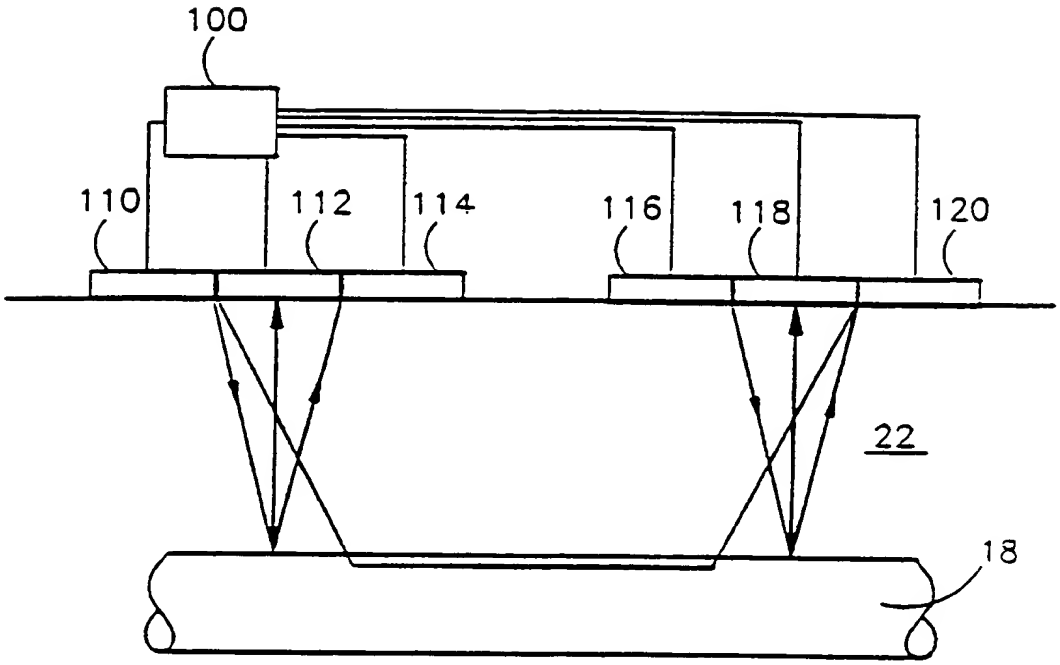


FIG. 7A

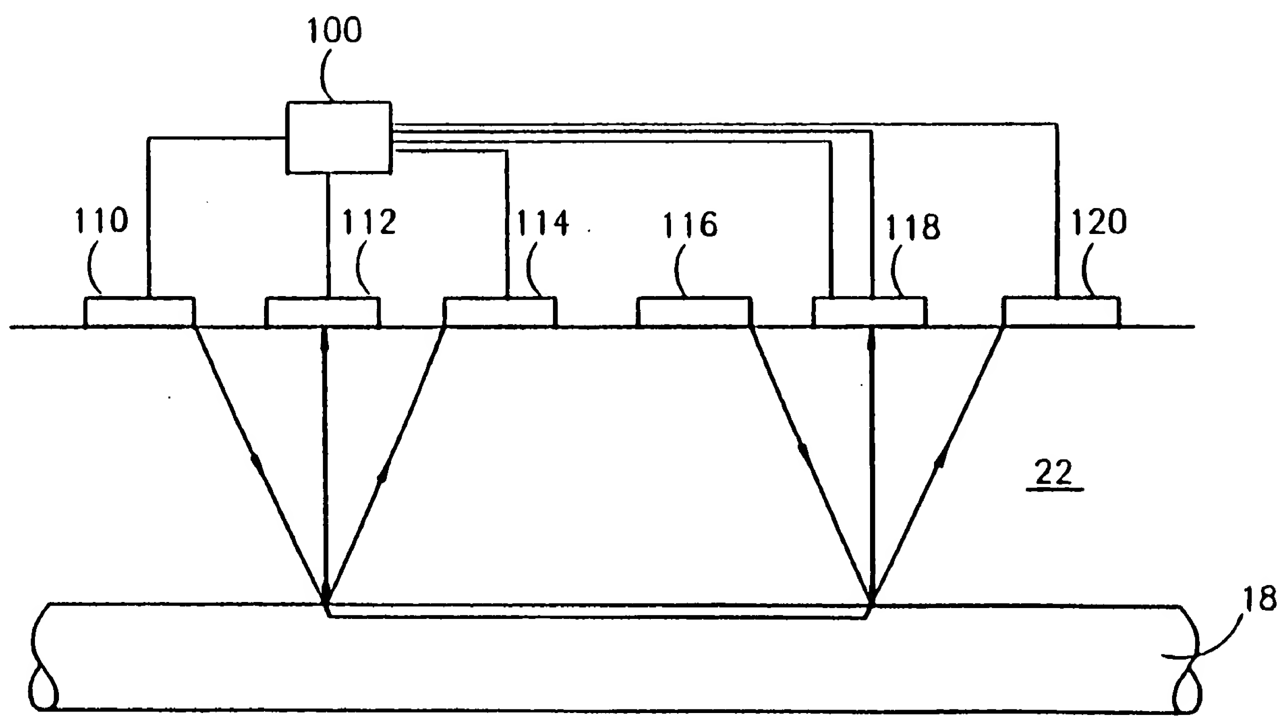


FIG. 7B

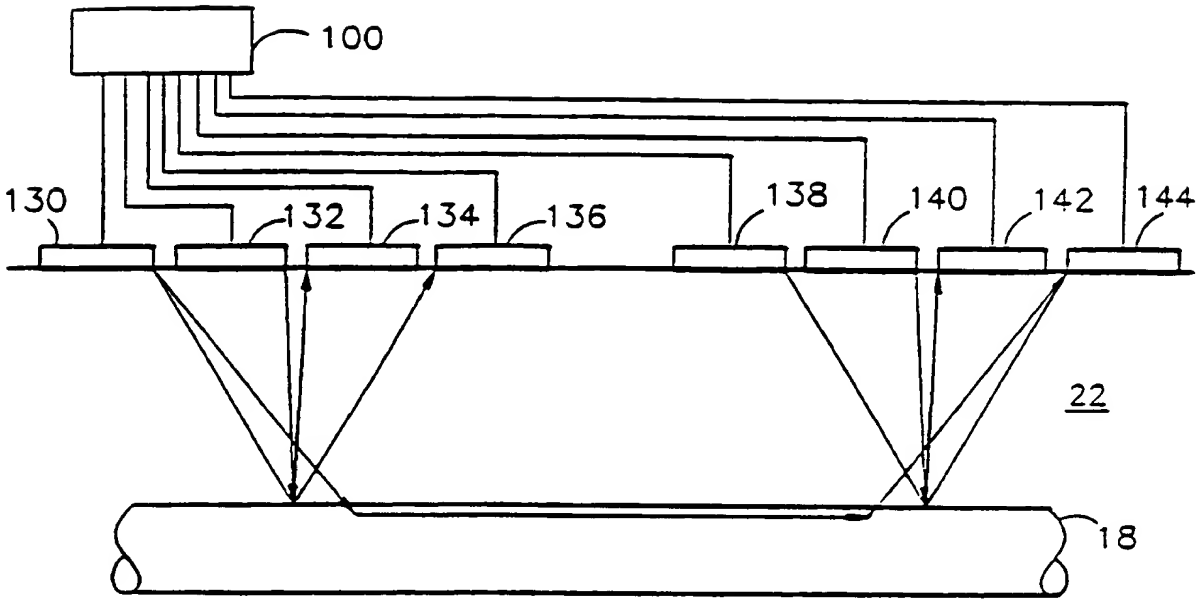

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FIG. 8A

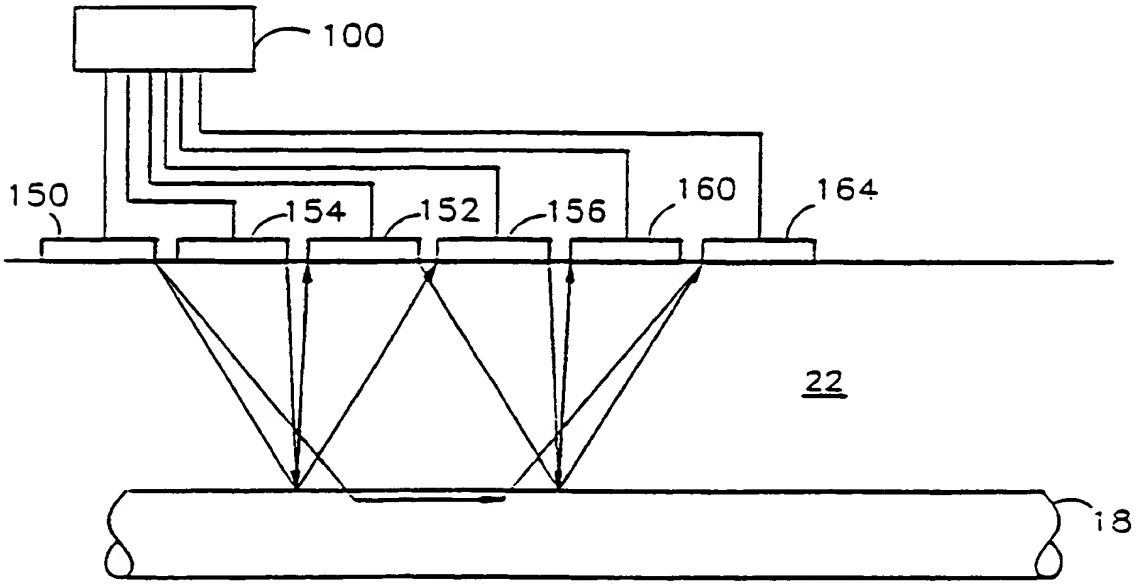
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FIG. 8B

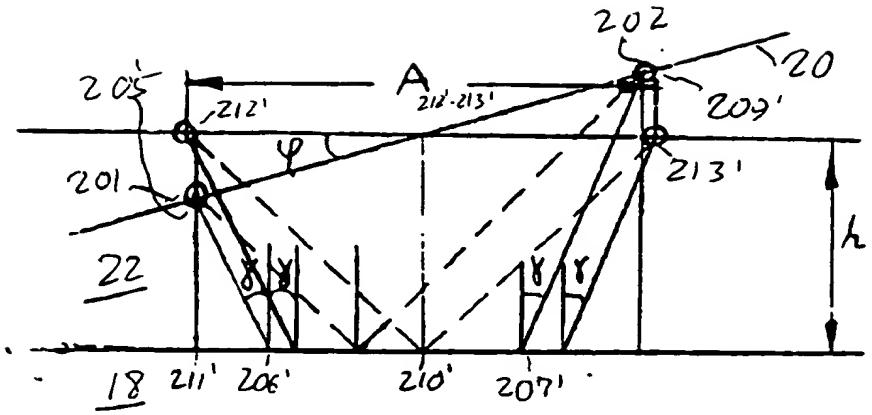


Fig. 8C

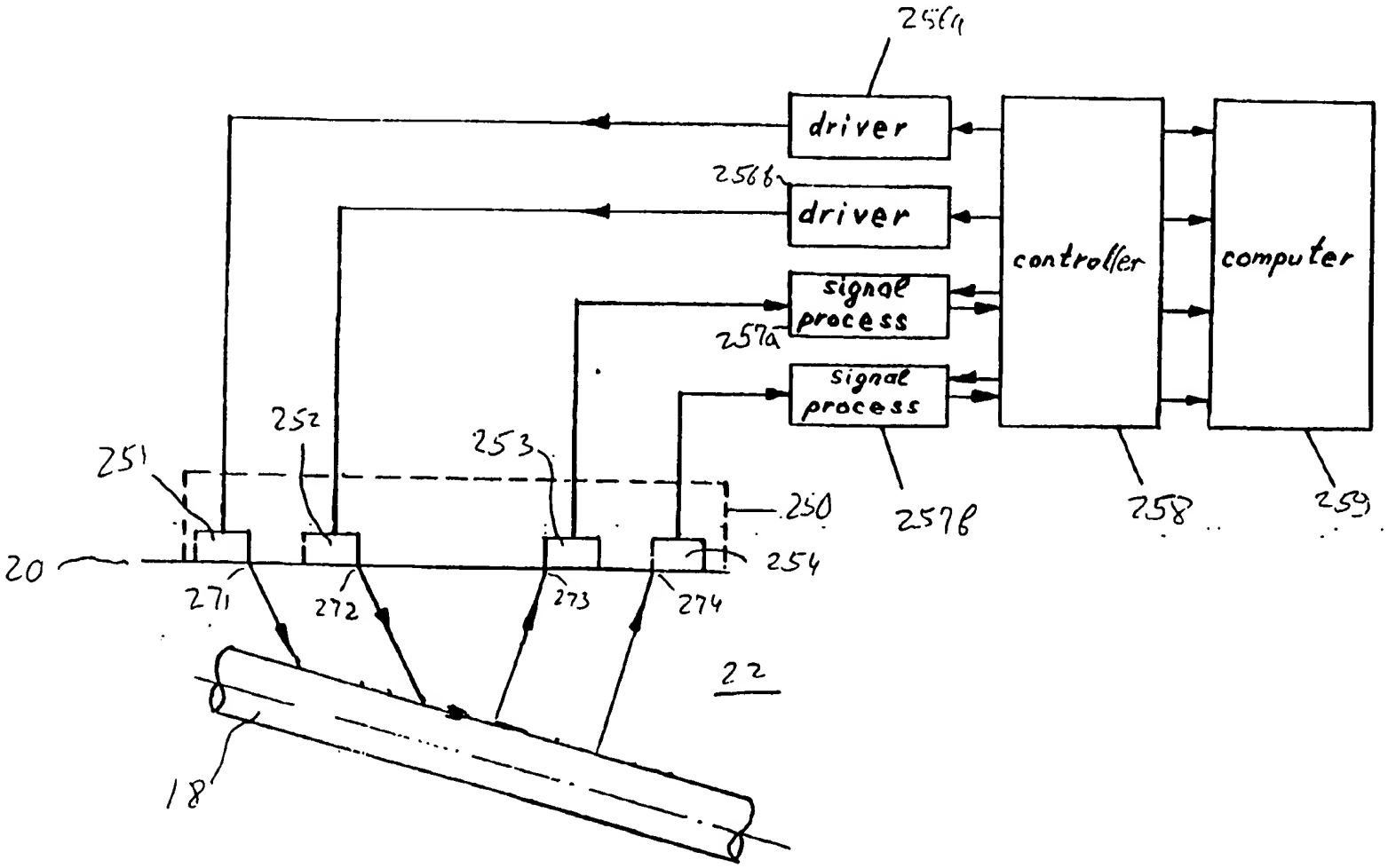


Fig. 8D

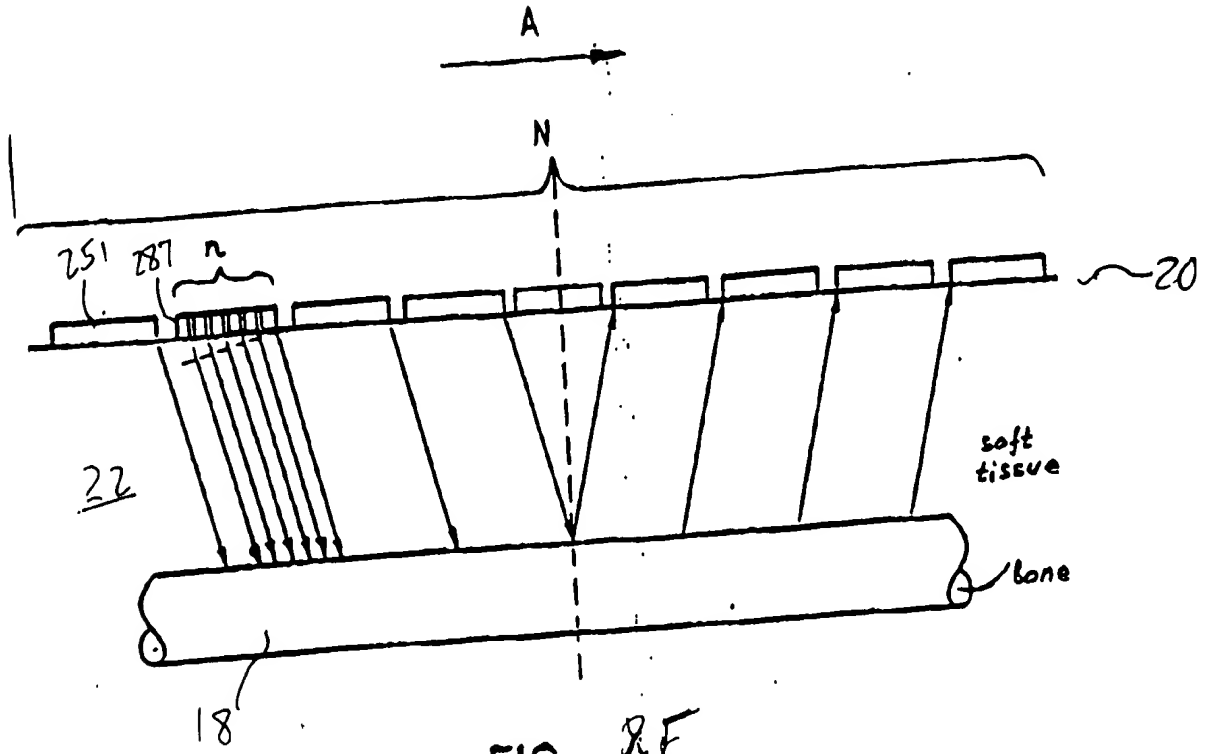


FIG. 8E

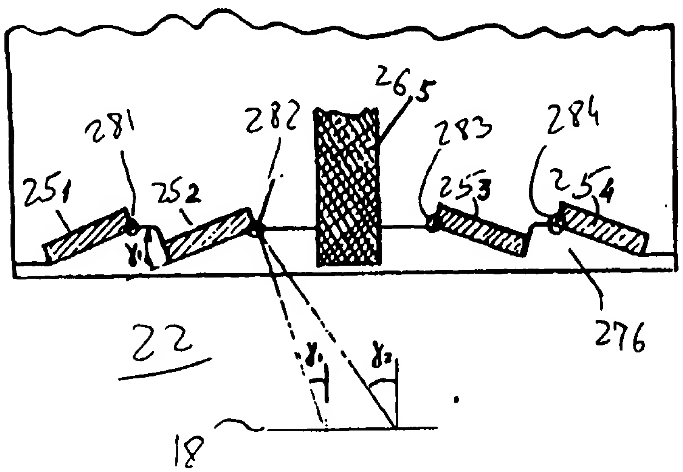


Fig. 8F

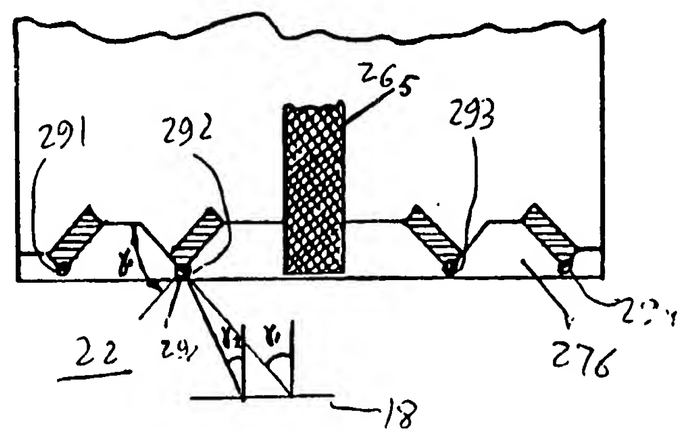


Fig. 8G

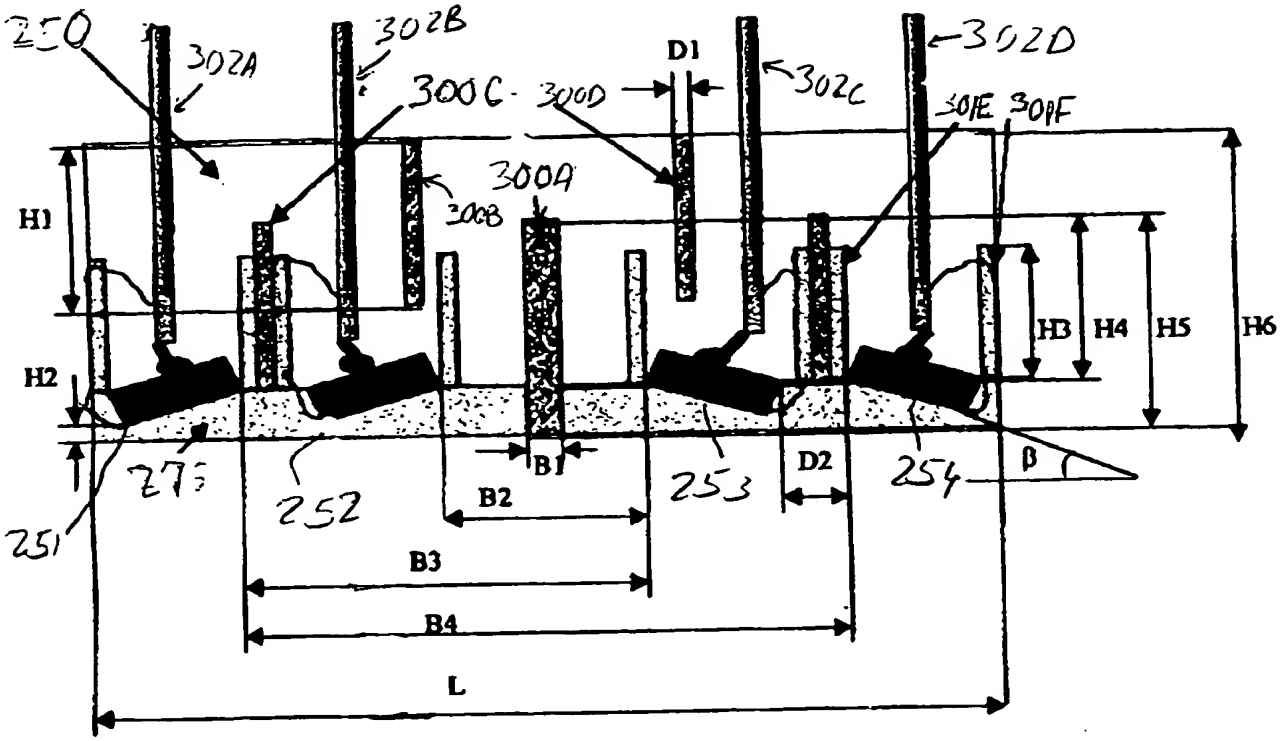

250
302A
302B
300C
300D
D1
302C
302D
30IE
30IF
300A
300B
H1
H2
H3
H4
H5
H6
273
252
B1
B2
253
D2
254
β
251
B3
B4
L

Fig. 8H

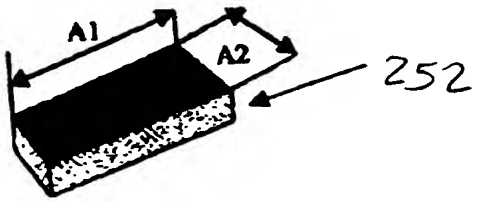

A1
A2
252

Fig. 8I

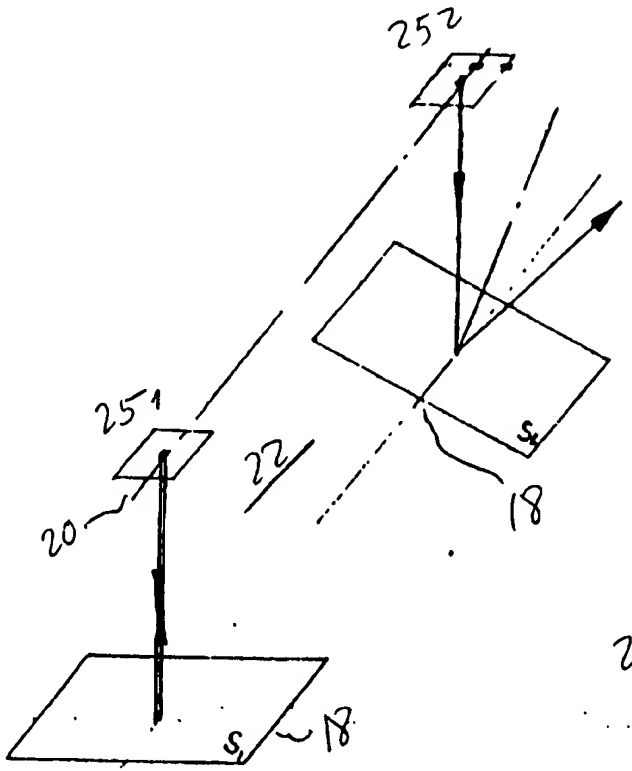


Fig. 8F

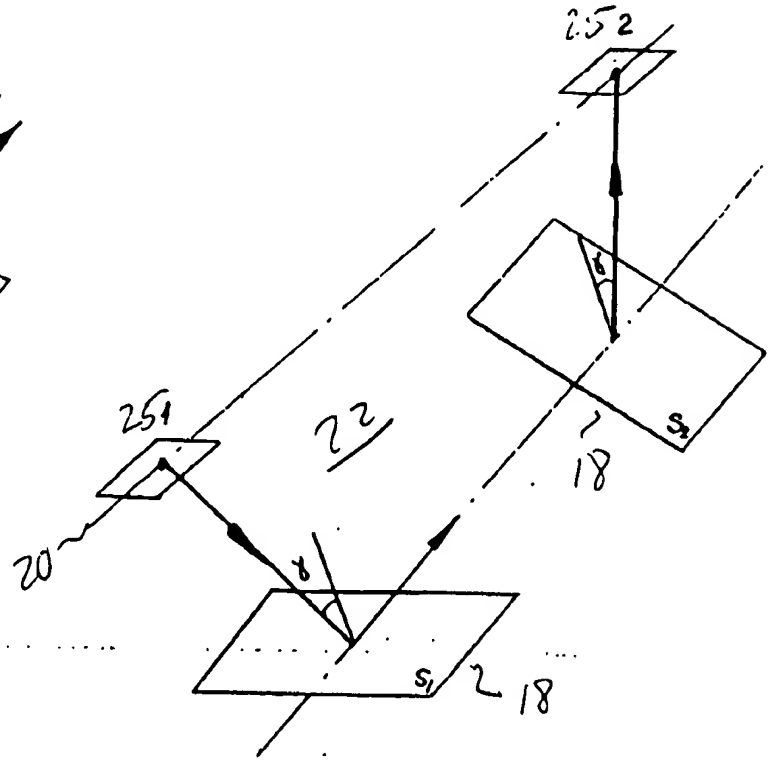


FIG. 8K

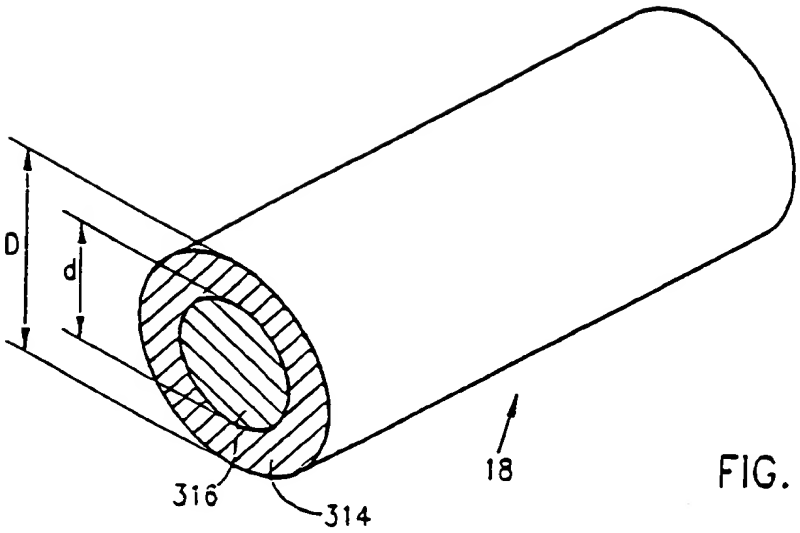
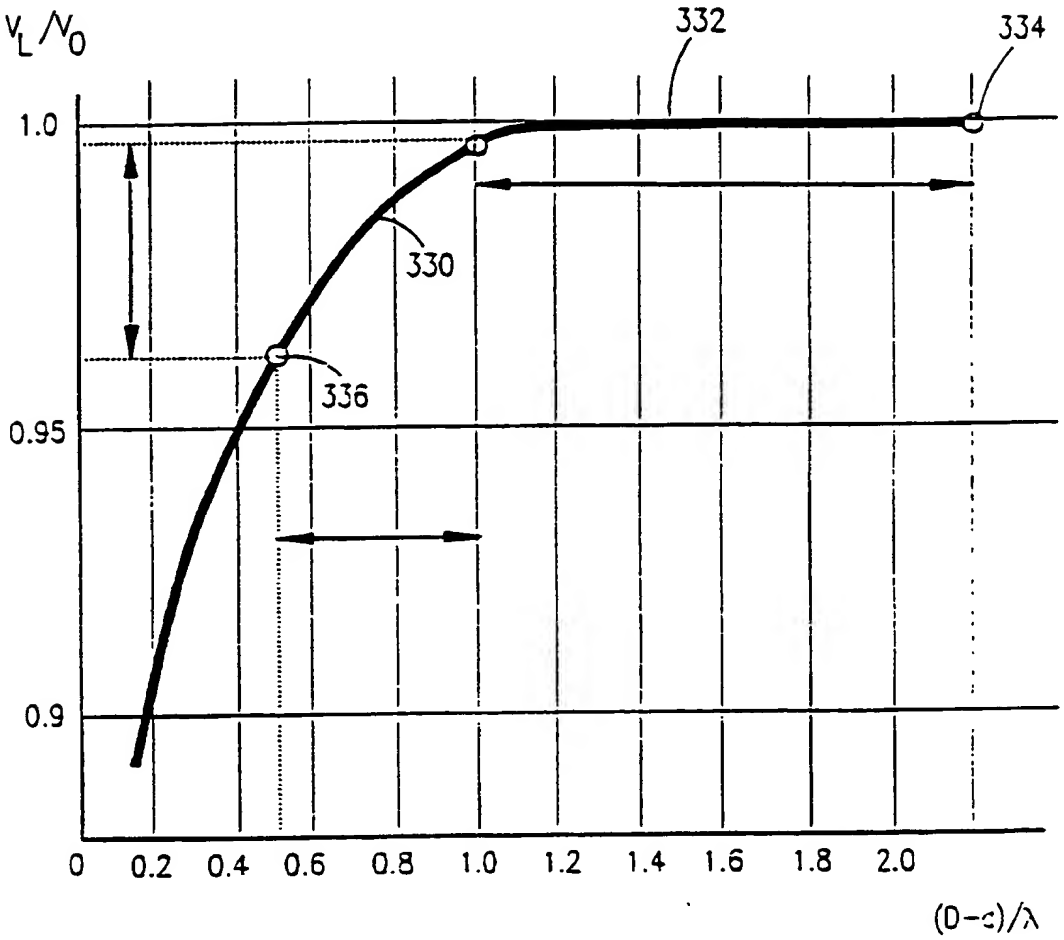


FIG. 9

FIG. 10


V_L/V_0
332
334
1.0
330
336
0.95
0.9
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8
2.0
$(D-c)/\lambda$

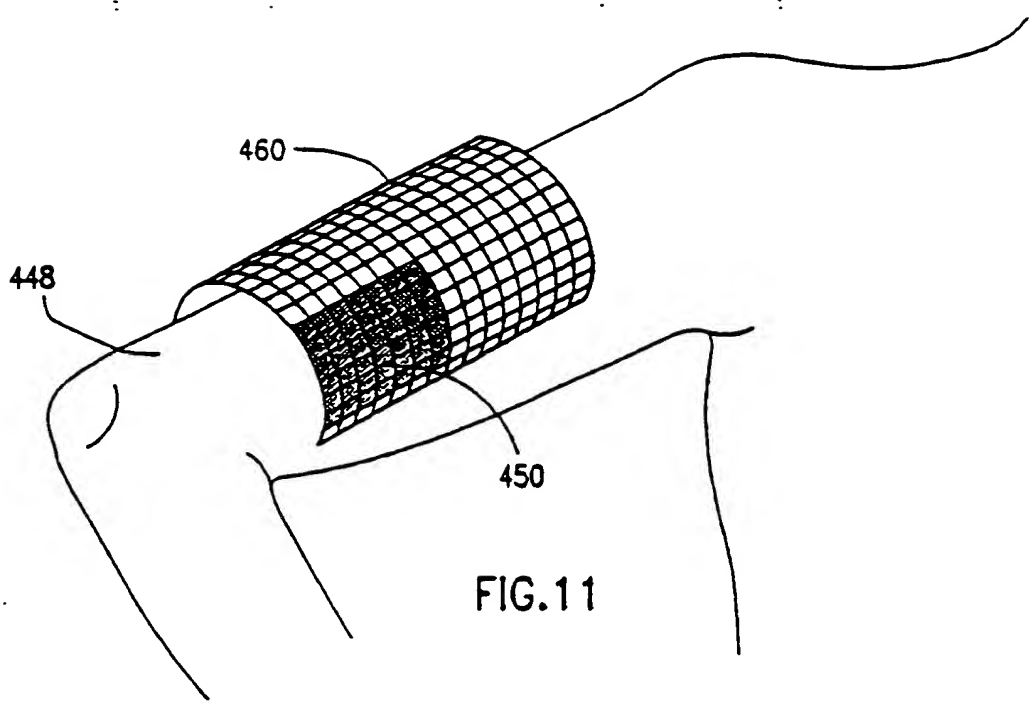

460
448
450

FIG.11

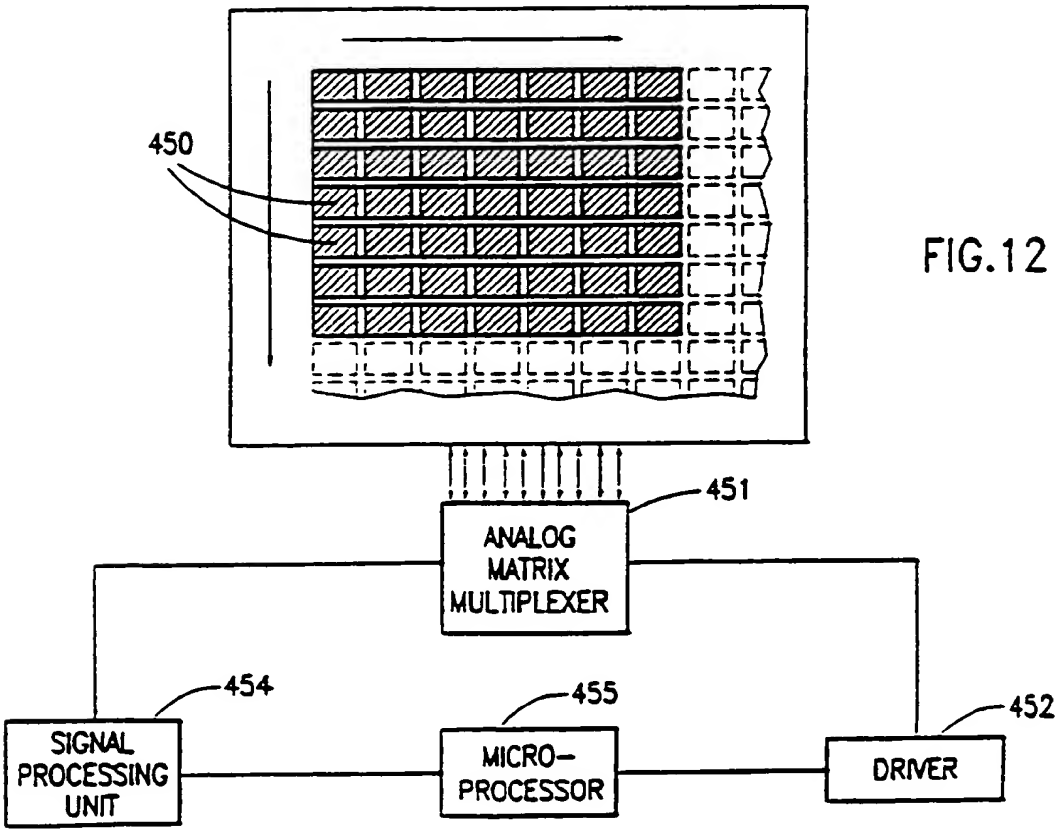
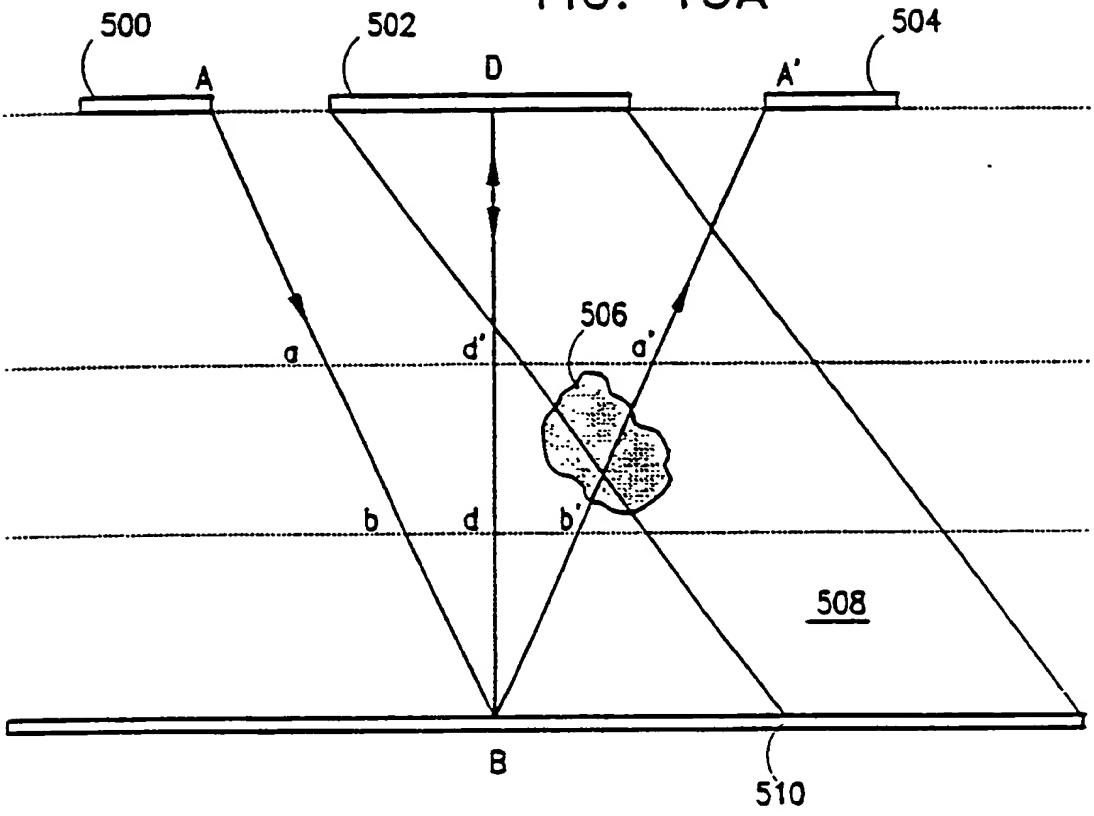

450
451
ANALOG MATRIX MULTIPLEXER
454
455
452
SIGNAL PROCESSING UNIT
MICRO-PROCESSOR
DRIVER

FIG.12

FIG. 13A



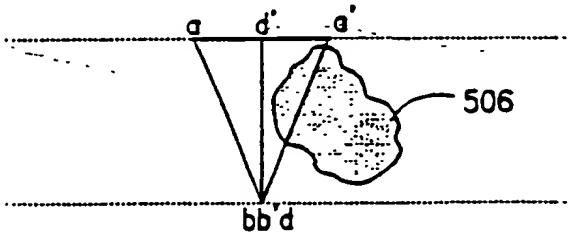


FIG. 13B

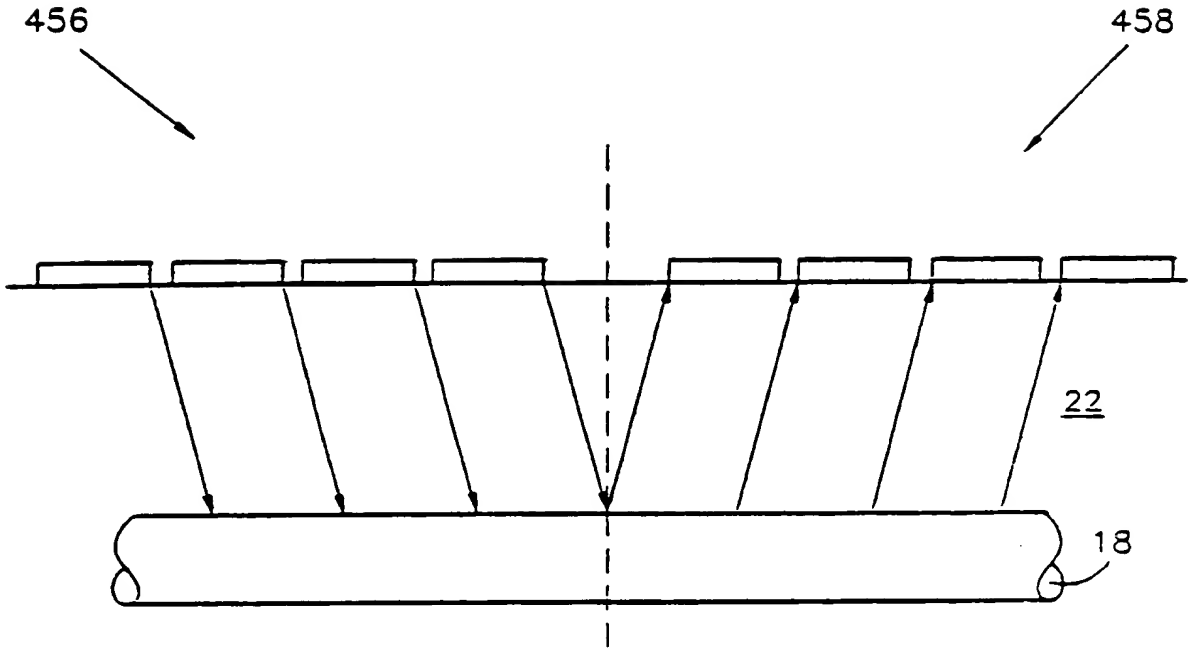


FIG. 14